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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-21

<u>TITLE</u>: Preparation and Revision of the IRIS Draft Toxicological Reviews of tert-Butanol (CASRN: 75-65-0) and ETBE (CASRN: 637-92-3)

Specify Section & Paragraph SOW: Assessment Issues and Documents 1. Human Health Assessment Documents. E. Risk Assessment Support F. Information Management

PERIOD OF PERFORMANCE: CO award to 10/31/14

I. PURPOSE

The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in the completion of revisions to the draft IRIS Toxicological Reviews of *tert*-butanol and ETBE. The overall objective of this WA is to provide administrative, logistical, and scientific support for draft development of the human health risk assessments for *tert*-butanol and ETBE. This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

II. BACKGROUND

IRIS is an EPA data base containing Agency scientific positions on potential adverse human health effects that may result from chronic (or lifetime) exposure to chemicals in the environment. IRIS currently provides health effects information on over 500 chemical substances.

IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for non-cancer health effects resulting from oral exposure (the RfD), the reference concentration for non-cancer health effects resulting from inhalation exposure (the RfC), and the carcinogen assessment for both oral and inhalation exposures. Combined with specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

EPA holds bimonthly public meetings to provide an opportunity for input and discussion on preliminary materials for IRIS chemicals prior to the development of the assessments. The objective of this public meeting is to obtain input from stakeholders and the public on the studies and data that may be used to characterize hazard and exposure-response relationships and to develop toxicity values. Specifically, EPA is seeking input on preliminary materials including draft literature searches and associated search strategies, evidence tables, and exposure-response arrays for chemicals prior to the development of the IRIS assessments.

The overall goal of the human health risk assessments is to provide scientifically-defensible reasoning for the choice of critical cancer and non-cancer effects due to chemical exposure, along with the literature and principal study(ies) that best represent and support that choice. The Work Assignment Manager (WAM) will provide technical direction as necessary.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, and statistics. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The contractor shall develop a Quality Assurance Project Plan (QAPP) for this work assignment for the EPA Work Assignment Manager's (WAM) and Quality Assurance Manager (QAM) approval. The workplan and QAPP shall be submitted simultaneously for approval. The Contractor must address in the QAPP how they are going to consider the use of existing data to carry out this task. Existing (or secondary) data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "EPA Quality Manual for Environmental Programs EPA CIO 2105-P-01-0", http://www.epa.gov/irmpoli8/policies/2105P010.pdf; "EPA Requirements for Quality Assurance Project Plans (QA/R-5)", http://www.epa.gov/quality/qs-docs/r5-final.pdf; and "A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information" and its Addendum, http://www.epa.gov/stpc/assess.htm.

The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan and QAPP are reviewed and approved.

Task 3: Technical Editing of the Draft Toxicological Review of tert-butanol and ETBE, and IRIS Summaries

The Contractor shall conduct technical edits of the Toxicological Review prior to release for public comment/external peer review and prior to posting on the IRIS web site. The Contractor shall also conduct a technical edit of the IRIS Summary prior to posting.

Technical editing, which involves the reworking of written technical material for a specialized audience, may include: arranging tabular material; assessing illustrations to determine clarity of presentation, need for redrawing, retouching, etc.; standardizing symbols; verifying and restyling reference citations where required; and cross-checking information in text, tables, and figures, as well as correcting errors in grammar, spelling, and punctuation. This work shall be performed according to EPA guidance related to the technical editing; the Handbook for Preparing NCEA Documents shall be used as a primary reference to resolve issues involving usage and style. All products will be formatted using current versions of IRIS Summary and Toxicological Review templates. The reference list shall be formatted according to the output in HERO (i.e., the HERO format supersedes the Handbook for Preparing EPA Documents). Technical editing includes:

- a. Mechanical editing Close reading of the manuscript to ensure correct grammar, spelling, syllabification, and punctuation; consistency of capitalization, spelling, and hyphenation; agreement of verbs and subjects; agreement of pronouns; correct use of adverbs and adjectives; beginning and ending quotation marks and parentheses; correct use of ellipsis; cross-checking contents with text to verify accuracy and consistency of headings, subheadings, and page numbers; and many other details of style.
- b. Substantive editing Involves any or all of the following: arranging or rearranging tabular material; assessing illustrations to determine clarity of presentation, need for redrawing, retouching, etc; standardizing symbols; verifying and restyling reference citations; cross-checking information in the text to tables, figures, appendices, and references and correct apparent disagreements; correcting inconsistencies in format and style.
- c. Checking references to ensure that all references cited in the text and only those references have been included in the reference section of the document and verifying accuracy, completeness, and adherence to established format. In the event that information is missing, consulting authors or procuring copies of cited material to complete reference.
- d. HERO links HERO links shall be added to any text in which links were not included.

The Contractor shall provide a final electronic mark-up (in 'Track Changes' format of Microsoft Word) of the draft Toxicological Review of Hexavalent Chromium and the IRIS Summary to the WAM no more than 20 days after receipt of the draft document from the WAM.

Task 4: Updates to Literature Search

The Contractor shall perform literature search updates during the review processes at regularly scheduled intervals during assessment development (i.e., through release for external peer review) and at least once after external peer review. The interval (i.e., number of months) between literature search updates shall be determined in consultation with the Contractor. The literature search strategy shall be consistent with the strategy for the initial hexavalent chromium literature search conducted by ICF and with the latest draft of the Handbook for IRIS Assessment Development. The Contractor shall add new references to HERO, tag references consistent with existing tags in HERO, and document the updated literature search strategy and findings.

If questions arise during the literature search and screening task (e.g., difficulties in narrowing down the number of "hits" from the search, questions about the relevance of certain types of papers or topics, retrieval of difficult to obtain documents or foreign language papers), the Contractor shall contact the WAM for further consultation.

Task 5: Maintenance of the HERO Database for tert-butanol and ETBE

The Contractor shall perform the following to ensure the HERO database is up to date with the most current Toxicological Reviews of tert-butanol and ETBE:

- Ensure that all literature referenced in the IRIS document can be found in HERO
- Ensure that references listed in HERO for a "tert-butanol" or "ETBE" search but are not referenced in the IRIS document do not contain tags that suggest otherwise
- Ensure that references are appropriately tagged, both in their HERO listings and in the hyperlinks embedded in the document
- Ensure that retrieved pdfs of references in the IRIS document are uploaded to HERO

OPTIONAL TASKS

The following tasks are optional. If EPA determines the services under these tasks are required, the EPA WAM will initiate by issuing written technical direction. These optional tasks should be addressed in the technical proposal and included in the cost proposal of the work plan.

Optional Task 6: Update and Quality Assurance of Evidence Tables

The Contractor shall provide support to EPA in performing updates and quality assurance checks of tables that summarize organ-specific toxicity in human studies and animal bioassays (i.e., evidence tables). Updates of evidence tables shall be performed to add new studies identified through literature search updates performed during development of the draft assessment or during review steps. Quality assurance checks shall include the following: comparison of table entries to information from the original publication, checking conversions as appropriate (e.g., ppm to mg/m³), confirming effect levels, and inserting and verifying HERO links. For each health effect category, separate evidence tables will be developed (if data are available), and all routes of exposure will be considered, including inhalation, oral, and dermal. The quality assurance check should be performed by a scientist that was not involved in the initial development of the table being reviewed. These tables will be provided to the Contractor by the WAM.

Optional Task 7: Additional Dose-Response Modeling

Additional endpoints may be identified by the WAM that need to be modeled. The Contractor shall use the most recent version/updates of EPA's BMDS. The Contractor shall:

- i. Model all endpoints as identified by the WAM, where the data set supports modeling.
- ii. Identify data that may not be amenable or reliable to model.
- iii. Identify important or unusual statistical uncertainties in the data or the fitted models.
- iv. Adhere to EPA's most recent BMD Technical Guidance¹ in conducting the modeling. If any exceptions to the guidance are used in an analysis (e.g., by disabling default parameter constraints) these exceptions should be noted and explained.
- v.Be cognizant of the information contained in BMDS help/training materials² when modeling the data or comparing models. Deviations may be allowed if adequately explained and justified to Agency experts.
- vi.For dichotomous data, derive three candidate points of departure (PODs) for each endpoint (i.e., BMDL10, BMDL5, BMDL1). For continuous data, derive PODs using a BMR of one standard deviation from the control mean.
- vii.For all models fitted, report, in a tabular format, key statistics for model goodness-of-fit (e.g., chi-square statistic and associated p-value) and model comparisons (e.g., Akaike's Information Criterion (AIC) value).
- viii.In conducting model comparisons and selecting models, EPA guidelines should be followed. Deviations may be allowed if adequately explained and justified to Agency experts.
- ix. In selecting models, the following guidelines should be adhered to, but deviations may be allowed if adequately explained and justified to Agency experts.

Testing goodness-of-fit

- a. The chi-square goodness-of-fit p-value should be > 0.1.
- b. All chi-squared residuals < 2.0.
- c. By visual inspection, the model should exhibit a reasonable fit to the data.

Model selection

a. Models with the lowest AICs are preferred. Models with AICs that differ by less than 0.5 or so are generally considered not significantly different from one another.

Optional Task 8: Preparation of Exposure-Response Arrays

² U.S. EPA NCEA supra note 1.

¹ U.S. EPA (2000) National Center for Environmental Assessment, Benchmark Dose Technical Guidance Document. Available from: http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=22506

The Contractor shall develop exposure-response arrays, i.e., figures that provide a visual display of information in evidence tables. In general, a figure will be developed for each health effect category, with separate figures developed for oral and inhalation study information. The Contractor shall consult with EPA to determine the data sets to be represented in each array and the order of these data sets on the array. At present, EPA is typically using Microsoft Excel for generating these arrays. The Contractor may be asked to consider alternative software for generating these figures.

Optional Task 9: Support in Addressing Comments on the Toxicological Reviews following the Public Biomonthly Meeting and Various Review Steps

The Contractor shall provide support to the EPA in addressing comments received during the public bimonthly meeting and various review steps, including Agency review, interagency review, external peer review, and public comment. EPA cannot anticipate the number or nature of comments that will be received at each review step or the specific type of Contractor support that will be required following any given review step. EPA estimates that support may consist of the following tasks: summarize comments by topic or issue, research special topics or issues that may be raised in comments, conduct additional BMD or other modeling/analysis as appropriate, revise the Toxicological Review in response to comments, and assist in developing written responses to comments. The Contractor may also be asked to populate Comment-Tracker, an Access database developed by EPA to manage comments (and responses) on the draft assessment. The Contractor may also be asked to attend the interagency review meeting (via teleconference) and take notes during that meeting for internal use. All of these tasks will require a quick turn-around time.

Optional Task 10: Preparation of IRIS Summary

Prior to final Agency review and interagency science discussion, the Contractor shall prepare the IRIS Summary. The IRIS Summary shall be developed using the latest IRIS Summary template (to be provided by the WAM) and instructions for IRIS Summary development in the SOPs. The IRIS Summary shall be generated by extracting appropriate text from the current draft Toxicological Review (i.e., the draft that reflects revisions in response to external peer review comments). Little new writing will be required. The WAM will provide the Contractor with the appropriate draft of the Toxicological Review to use in developing the IRIS Summary. The Contractor shall submit the draft IRIS Summary to the WAM for review.

The WAM will provide to the Contractor EPA's comments on the draft IRIS Summary. The Contractor shall revise the IRIS Summary based on EPA's comment and submit the revised final draft IRIS Summary to the WAM.

Optional Task 11: Study Quality Evaluation and Documentation

The contractor shall provide support to EPA in evaluating and documenting study quality. The Contractor shall consult with EPA to determine to approach and criteria to be used. Documentation may be done in the Dragon database.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	15 days after award
Task 3: Technical Editing of the Draft Toxicological	No more than 20 days after receipt of the draft Toxicological
Reviews and IRIS Summaries	Reviews and no more than 10 days after receipt of the IRIS

	Summaries from WAM
Task 4: Updates to Literature Search	For each update, no more than 30 days after initiation of
	literature search
Task 5: Maintenance of the HERO Databases	To be performed concurrent with literature search updates
Optional Task 6: Update and Quality Assurance	No more than 7 days after discussion with WAM
of Evidence Tables	
Optional Task 7: Additional Dose-Response	No more than 7 days after discussion with WAM
Modeling	
	,
Optional Task 8: Preparation of Exposure-Response	No more than 7 days after discussion with WAM
Arrays	
Optional Task 9: Support in Addressing Comments	To be determined based on the nature of the Contractor support
on the Toxicological Reviews following Various	required
Review Steps	
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Optional Task 10: Preparation of IRIS Summary	7 days after final draft Toxicological Review is provided to the
	Contractor by EPA
Optional Task 11: Study Quality Evaluation and	No more than 20 days after discussion with WAM
Documentation	

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
- 2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Janice S. Lee

Telephone: 919-541-9458

Fax: 919-541-2985

e-mail: lee.janices@epa.gov

Mailing Address:

U.S. Environmental Protection Agency Mail code B-243-01 RTP, NC 27711

Overnight Delivery location: U.S. Environmental Protection Agency (B243-01) 4930 Page Road Durham, NC 27703

Alternate Work Assignment Manager:

Keith Salazar

Telephone: 703-347-0278

Fax: 703-347-8689

e-mail: salazar.keith@epa.gov

Mailing Address:
USEPA Headquarters
Ariel Rios Building
1200 Pennsylvania Avenue, N. W. *Mail Code:* 8601P
Washington, DC 20460

Overnight Delivery location: Potomac Yards North 2733 Crystal Drive Rm # N7845 Arlington, VA 22202

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-22

TITLE: NexGen Report

Specify Section & Paragraph SOW: A. Assessment Issues and Documents

PERIOD OF PERFORMANCE: CO approval through 10/31/14

I. PURPOSE

The purpose of this Work Assignment (WA) is to provide services to the US Environmental Protection Agency (EPA), Office of Research and Development (ORD), National Center for Environmental Assessment (NCEA), to summarize and respond to comments received on the NexGen Report, provide editing and additional content where necessary.

II. BACKGROUND AND OBJECTIVES

NCEA published the external review draft of its Next Generation Risk Assessment: Incorporation of Recent Advances in Molecular, Computational, and Systems Biology on September 30, 2013. The report outlines how NCEA anticipates incorporating new data streams into the risk assessment process, and provides illustrative case studies. We received comments from the public and peer reviewers.

NCEA is revising the report to incorporate feedback from the external peer reviewers, and will revise the report to be responsive to external comments. Responses will require significant addition of text, and significant editing of existing text. It may also require the creation of new sections *de novo* to appropriately respond to some of the feedback we receive. We anticipate having a completed revision by June 30, 2014 and delivering the finalized product on September 15, 2014.

III. STATEMENT OF WORK

The contractor shall be responsible for a range of tasks. A summary of each task is provided below, including the time frame during which the task shall be completed.

Task 1: Summarize all public comments into general themes.

The contractor shall:

- Arrange a meeting with the EPA WAM, key EPA and ICF staff to develop a plan to accomplish this task
- Summarize all public comments into general themes
 - Associate specific comments with the appropriate theme(s)
 - Prepare a MS Excel spreadsheet that lays out the comment themes, the associated specific comments, the individual who made the comment, their specific affiliation, and a general category of their affiliation (e.g., industry, general public, government, public health advocacy group, etc...)

- Prepare, review, and finalize the external peer review summary:
 - o As a MS Word document with tables for each general theme, suitable for use as an Appendix to the Report
 - o As the MS Excel spreadsheet described above

Task 1	Descriptions	Date
	Arrange a meeting with the EPA WAM, key EPA and ICF	Completed within 10
	staff to develop a plan to accomplish this task	business days of
		award
	Prepare, review, and finalize the public comment	Completed by
	summary	March 14, 2014

Task 2: Science and technical editing of the revised report

The contractor shall perform science and technical editing of the report, to include combining of scientific edits submitted by EPA authors, alignment of tone and voice, checking for accuracy of spelling and typographical errors, and ensuring the overall document quality is of sufficient quality, generally to mean that the document is free of errors and is accurate. During the science edit, the contractor shall also assist with revisions to the Executive Summary to ensure it is written in plain language and is appropriate for the audience (e.g., risk managers).

EPA will provide a draft for a first round science and technical edit by March 12, 2014. The first round edit will be performed, checked and verified by the EPA, and a second final edit will be performed. EPA will provide the contractor a draft for a second final edit by June 1, 2014. These edits by the contractor shall also include ensuring the images in the document meet the quality and production standards of the EPA (which may include flattening of image objects to create a single image) and the final draft document will be able to be converted to 508 compliant PDF format.

Task 2	Description	Date		
	Complete initial round of science and technical edits	Completed by April 11, 2014		
	Complete final round of science and technical edits	Completed by June 20, 2014		

Task 3: Draft of plain language article suitable for publication

The contractor shall:

- Arrange a meeting with the EPA WAM, key EPA and ICF staff to develop a plan to accomplish this task
- Draft a plain language article (e.g., targeted toward a college educated audience) based on the "Next Generation Risk Assessment: Incorporation of Recent Advances in Molecular, Computational, and Systems Biology" report that is suitable for publication and submit to EPA WAM for review.
- Complete revisions based on suggestions provided by EPA WAM and submit a revised plain language article to the EPA WAM.

Task 3	Description	Date
	Draft plain language article suitable for publication	Completed by
		May 30, 2014
	Revised plain language article	Completed by
		July 30, 2014

IV. Notice Regarding Guidance Provided Under this Work Assignment:

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or WA, the contractor shall immediately notify the WAM. The contractor shall also ensure that work under this Task Order does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that no conflicts exist at the time the proposal is submitted to the EPA.

V. Instructions to the Contractor

Assumptions made in the preparation of the work plan shall be explicitly stated.

VII. EPA Contact Information

Electronic copies of all correspondence pertaining to the performance of this WA shall be sent electronically to the EPA PO.

Work Assignment Manager (WAM):

Rob DeWoskin
Hazardous Pollutant Assessment Group, Research Triangle Park Division
National Center for Environmental Assessment
U.S. Environmental Protection Agency
(919) 541-1089; DeWoskin.Rob@epa.gov

Alternate Work Assignment Manager (Alt-WAM):

LCDR Eva D. McLanahan
Hazardous Pollutant Assessment Group, Research Triangle Park Division
National Center for Environmental Assessment
U.S. Environmental Protection Agency
(919) 541-1396; McLanahan.Eva@epa.gov

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-23

TITLE: Development of Population/Migration Scenarios

Specify Section & Paragraph SOW: E. Risk Assessment Support
1. Science Writing, Risk Communication and Training and 2. Administration and Technical Support for NCEA Human Health Related Meetings

PERIOD of PERFORMANCE: CO approval through 10/31/2014

I. PURPOSE

The purpose of this work assignment is to provide scientific and technical support for the development of population/migration scenarios, to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA). This work assignment is consistent with the purpose and scope of Contract EP-C-09-009 and includes summarizing the relevant literature and preparing background material on the current state of knowledge with respect to population projections, especially projections of migration patterns, providing technical expertise to a workshop planning committee, participating in an experts-only workshop, and preparing a draft summary of the workshop.

II. BACKGROUND

Population change plays a critical role as both a driver of global and environmental change and as a determinant of vulnerability to that change. More specifically, scenarios of future population are needed for climate change health assessments. The US Global Change Research Program (USGCRP) National Assessments led to concerted efforts to develop population projections. However, while there are well-established methods for developing population projections, the USGCRP has not engaged in a sustained effort to develop population scenarios that are regional in focus but consistent with global-scale climate scenarios (e.g., IS92 Scenarios, SRES Scenarios). Developing scenarios of changes in population at fine spatial scales, including demographic characteristics, would support multiple agency needs including:

- Assessments of climate change impacts on human health, on water resources, on agriculture and forestry, coastal areas, natural resources, etc.; and
- determining vulnerability of people and infrastructure to climate and weather extremes.

The EPA would like to develop these scenarios with broad-based input from other federal agencies and academic experts. To that end, EPA is collaborating with the Department of Energy, which is holding a workshop on Population Scenarios. EPA is also working other federal agencies through an interagency working group of the US Global Change Research Program to develop content for the workshop. A steering committee will be established to facilitate coordination between EPA and other agencies for this effort.

The workshop is intended to bring together a group of experts from different backgrounds to identify:

1) End Uses. Characterize end uses for population/migration scenarios, and narrow the set to high priority end uses that will inform near team foci within the workshop and subsequent activities.

- 2) **Drivers.** Identify key natural, physical, socioeconomic, and policy variables affecting population/migration change.
- 3) Capacity. Inventory existing data, modeling, analysis, and methodological capabilities that can be leveraged and serve as foundational resources.
- 4) Gaps. Identify key gaps in data, modeling, and analysis capacity, etc. related to population/migration to inform future research needs.
- 5) **Observational Intersects.** Explore the unique contributions and intersections of both observationally-based and modeling based-methods for evaluating population/migration and projecting future change.
- 6) **Scenario building**. Construct preliminary population/migration scenarios to gain insights into framing, contextual variations, methodological approaches, and paths forward for developing U.S population/demographics focused scenarios.
- 7) **Community building.** Create the foundations for a community of practice and sustained effort in the science, methodologies, tools, and applications of population/migration scenarios.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, that shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, and statistics. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of existing data to carry out this task as well as how they are going to evaluate models. Existing data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs" and "EPA Requirements for Quality Assurance Project Plans (QA/R-5)". Guidance from the Council for Regulatory Environmental Modeling (CREM) relating to models and model evaluation can be found at: http://www.epa.gov/crem/cremlib.html.

Task 3: Collect Information on Other Agency Models that Require Future Population/Migration Projections

The Contractor shall research the types of models and analyses that are used within EPA and by other Federal Agencies with respect to how projections or assumptions regarding future population trends and migration patterns are incorporated. The Contractor shall prepare a memo that briefly describes each of these models and their data needs with respect to future populations and construct a spreadsheet with relevant attributes. The

Contractor shall provide the memo and spreadsheet to the EPA WAM for review and approval

Task 3 within 10 weeks after receipt of WP approval.

Task 4: Collect Background Information for the Development of Future Scenarios

The Contractor shall prepare background information on future scenarios as follows:

- (a) Expert Opinion Elicitation: The Contractor shall elicit expert opinions from several fields that the Contractor deems necessary through his expertise, to gather information on potential future trends in: economics, society, technological innovation, geo-politics, political trends in the US, environmental amenities (including climate) and their potential relation and impact on population and population migration. The WAM will provide recommendations, if needed, as to possible experts whose opinion the Contractor may elect to elicit. The Contractor shall advise the WAM (verbally or electronically) when this portion of Task 4 has been completed, no later than two months after receipt of WP approval.
- (b) Existing data, modeling, analysis, and methodological capabilities: The Contractor shall summarize in spreadsheet format existing data, models and methodological capabilities that could be used in the development of future population/population migration scenarios. The Contractor shall provide the summary and spreadsheet to the WAM for review and approval within 2 months of receipt of WP approval
- (c) The Contractor shall draw up a list of suggested readings on future population scenarios from peer-reviewed journals, periodicals, books and other sources that the Contractor deems relevant through his expertise. The Contractor shall provide this list to the WAM for review and approval within 2 months of receipt of WP approval.
- (d) <u>Preparation of Draft Background Materials</u>: The Contractor shall send the WAM an electronic copy of a draft of the background materials for comment. Background materials shall include:
 - i. A summary of selected uses of population projections in Agency models and analyses (as specified in Task 3)
 - ii. A list of suggested readings (as specified in Task 4, part (c), with the corresponding references in electronic format attached).
 - iii. A summary of existing data, modeling, analysis and capabilities (as specified in Task 4, part (b))
 - iv. A summary of relevant results from the expert opinion elicitation from Task 4 part (a)

Task 4 (d) shall be completed within 10 weeks after receipt of WP approval

(e) <u>Final draft background materials</u>: The EPA WAM shall provide comments on the background materials and the Contractor shall prepare a final draft of the background materials and provide an electronic copy to the WAM no later than 1 month before the DOE workshop.

Task 4 (e) shall be completed 1 month prior to the workshop.

Task 5: Webinars

Prior to the DOE workshop, up to eight webinars will be given. These will be presentations on technical topics as determined by the steering committee. Working with the steering committee the EPA WAM will provide the contractor with a list of presenters. The contractor shall arrange logistics for these webinars, provide for

recording of the presentations, and take notes during these presentations for inclusion in the workshop report.

Task 5 shall be completed within 2 months after receipt of presenters list from the EPA WAM.

Task 6: Population Workshop Participation and Preparation of draft post-workshop report.

The Contractor shall attend and participate in the DOE Population Workshop as an expert. The tentative time frame for the workshop is June 2014. The Contractor shall arrange for notes to be taken for all sessions. Working with the WAM, the Contractor shall acquire any additional notes from other workshop participants.

- (a) <u>Prepare outline:</u> In consultation with the EPA WAM, the Contractor shall prepare an annotated outline of the post-workshop report and provide it to the EPA within 5 days of the end of the Workshop. The EPA WAM will review and approve the report outline.
- (b) <u>Draft report</u>: The Contractor shall prepare a draft report based on: 1) input received on the outline (Task 6a), 2) at the workshop (Task 6); 3) webinars (Task 5) and 4) background materials (Task 4). The Contractor shall provide the draft report to the EPA WAM within one month of receipt of comments on the outline.

Task 6b shall be completed within 1 month after receipt of EPA WAM comments on the outline

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. SCHEDULE OF DELIVERABLES

Deliverables Due Dates Task 1. Initial Conference Call 3 days after award of Work Assignment Task 2. Staffing Plan, and QAPP 15 days after award 3. Memo and database on models and analyses that use population scenario-type data 10 weeks after WP approval 4a. Expert opinion elicitation 2 months after WP approval 4b. Summary and database on models that could be used to develop population scenarios 2 months after WP approval 4c. Suggested reading list for participants 2 months after WP approval 4d. Draft background materials for workshop 10 weeks after WP approval 4e. Completion of background materials 1 month before workshop 5. Webinars 2 months after receipt of list of presenters 5 days after workshop 6a. Workshop participation and annotated outline

6b Draft post-workshop report Note: All days are calendar days.

1 month after receipt of comments

VI. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
- 2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM)

Anne Grambsch U.S. EPA Mail Code 8601 P Washington, DC 20460 (703) 347-8521; FAX (703) 347-8694 grambsch.anne@epa.gov

Alternate Work Assignment Manager (WAM)

Phil Morefield U.S. EPA Mail Code 8601 P Washington, DC 20460 (703) 308-1835; FAX (703) 347-8694 morefield.philip@epa.gov

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	All Mill 2/7/14								Phone Number: 513-487-2852			

PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-24

TITLE: Exposure assessment of livestock carcass disposal options

Specify Section & Paragraph SOW: A2 Exposure Assessment Documents.

I. OBJECTIVES

The main objectives of this Work Assignment (WA) are to determine:

- Hazards associated with livestock carcass disposal options following a natural disaster, Foreign Animal Disease (FAD) outbreak, or other potential cause for massive carcass disposal of livestock
- Exposure pathways associated with each identified carcass disposal option
- Calculated exposures for each exposure pathway with sufficient data to quantify
- Levels of uncertainty in the calculated exposures
- Carcass disposal options that are the least likely to result in exposure impacts to additional livestock, human health, and/or the environment
- Knowledge gaps for further study to help minimize uncertainties in the assessment

II. BACKGROUND

The U.S. Environmental Protection Agency's (EPA's) National Homeland Security Research Center (NHSRC) was established to conduct research in support of indoor/outdoor decontamination and water security. Specifically, NHSRC is responsible for assessing potential exposures associated with the intentional or accidental release of hazardous and toxic materials including chemical, biological, and nuclear agents. NHSRC is currently developing tools, technologies, and methods to aid and support this effort. One of the highest priorities of NHSRC is the applications of risk assessment methodologies that can be utilized to support decision making regarding cleanup goals, treatment technology efficacies, detection limits, and waste management options during biological contamination incidents.

Under the National Response Framework, EPA is a support agency for federalized responses to Foreign Animal Disease (FAD) outbreaks, providing support to the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA/APHIS). One of the likely areas where EPA might provide support to USDA/APHIS is in helping to assure the proper disposal of animal carcasses following major event such as a natural disaster or FAD outbreak. Currently, there are several accepted carcass disposal options including rendering, composting, sanitary landfills, permitted incinerators, open burning, and unlined burial (Figure 1). Given the incident-specific nature of a massive carcass disposal response, there are knowledge gaps in comparing these disposal technologies from environmental, cost, human health, and animal health standpoints. Developing a risk-based methodology to allow decision makers to select the most appropriate carcass disposal technology for a given incident would significantly improve the Nation's preparedness.

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		Car	cass D	isposal C	ptions	Processo	es		
Rendering				transport to rendering		grind carcasses	cook	manage steam, tallow, and meal	
Sanitary Landfill	×		* **	transport to landfill		bury carcasses	landfill	leachate, gas, and lids	Human, Ecological, and Livestock Health Risks
Permitted Incinerator	Load animal into truck	Cover truck	decon outside of truck	transport to incinerator	unload truck	load animals into incinerator	process	manage air emissions and ash	and Livestoc
Composting	Load an	8	decon o	transport to compost area	un .	build windrows		finished npost	, Ecological,
Open Burning				transport to burn site		burn carcasses	_	leachate, d smoke	Human
Unlined Burial				transport to burial site		bury carcasses		methane eachate	

Figure 1. Potential carcass disposal option processes to evaluate for associated hazards and exposure pathways.

III. TASKS

Task 1: Workplan

The contractor shall generate a workplan describing how tasks 2-6 shall be performed. The workplan shall include the overall project purpose, scope, and approach. Each task shall be described in detail including the specifics of the personnel projected to complete each task indicating the level of expertise required, personnel labor hours, timelines to complete each task, projected costs of each task, equipment and supplies required, facilities to be used, specific standard operating procedures (SOPs) (or location of SOPs on-site if considered proprietary business information), standards and controls used for compliance with quality assurance, data analysis and calculations to be utilized, safety considerations, and the risks associated with each task along with proposed mitigations. The workplan shall outline the tasks and subtasks along with timelines projected for completion of each task and task inter-relationships.

Deliverables: Workplan and Project Management file

Task 2: Quality Assurance Project Plan (QAPP)

The contractor shall develop a Quality Assurance Project Plan (QAPP) to describe data quality objectives and data usage requirements for this effort. The contractor shall demonstrate in the QAPP how the organization shall plan, implement, and assess the effectiveness of its quality assurance and quality control procedures. The QAPP should incorporate a test plan to outline how the research shall be conducted and the measures taken to ensure data quality using the appropriate practices. This WA is a QA Category II Project and shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5" detailed in Appendix A. The contractor shall not perform work under Task 3-6 until the QAPP is reviewed and approved by the EPA WA-COR. The contractor may begin work on Tasks 1 and 2 upon receipt of this WA. The contractor is responsible for the quality of the work, data and/or measurements of any potential subcontractors. The process the contractor shall use for assessment of quality standards and measurements performed by any subcontractor shall be addressed in the QAPP.

The contractor shall provide QAPP document preparation and revision(s) as well as maintaining any additional quality assurance paperwork, including required SOPs or records of work performed. The contractor shall ensure that the products are responsive, timely, and of high quality to meet the requirements of the Agency. The contractor shall ensure that this documentation is maintained in an appropriate fashion, and make this documentation available for inspection by the EPA WA-COR, the EPA Quality Assurance Manager or others as designated by these individuals. All supporting documentation shall be referenced and attached.

Deliverable: QAPP

Performance Standard: The contractor shall provide the draft QAPP containing all required elements mentioned above within 30 days of award.

Task 3: Exposure Assessment Problem Formulation

The contractor shall draft the problem formulation document describing the purpose and scope of the exposure assessment by identifying a basic assessment framework (including the determination of boundaries of the assessment), necessary data or model inputs and outputs, and the key assumptions. The complexities and final scope of the exposure assessment including which identified hazards and disposal options to evaluate will be determined by the WA-COR and project team. The exposure assessments will most likely be completed in phases as follows:

- 1. Comparison of carcass disposal options after natural disaster
- 2. Comparison of carcass disposal options after FAD, Foot and Mouth Disease (FMD)
- 3. Comparison of carcass disposal options after chemical exposure, Dioxin
- 4. Comparison of carcass disposal options after radiological exposure
- 5. Presentations of assessment results at series of expert workshops

The contractor shall estimate the cost broken down into each of these exposure assessment phases. The project team, WA-COR, and contractor will discuss options for the complete exposure assessment prior to the completion of the problem formulation document. The problem formulation document shall include but is not limited to the following sections:

- Statement of Purpose
- Questions to be Addressed
- Scope

- o Hazard Identification and Screening
- o Receptors (Livestock, human, and/or environment)
- o Endpoints of Assessment
- o Exposure Durations and Units of Exposure

Deliverable: Problem Formulation Document

Performance Standard: The contractor shall provide the draft problem formulation document within 3 months after approval of work plan and QAPP.

Task 4: Carcass Disposal Options Processes Conceptual Models

The contractor shall develop conceptual models for each of the identified carcass disposal options for each phase of the project. The conceptual models will qualitatively describe the disposal options processes to describe suspected sources, potential pathways of exposure, and potential receptors. The models shall concisely convey the underlying assumptions of the exposure assessment and how the exposure of receptors will be modeled to occur. The carcass disposal options conceptual models shall be developed based on available information regarding the potential fate, transport, and exposure route.

Deliverable: Conceptual Models Document

Performance Standard: The contractor shall provide the draft conceptual models document within 3 months after approval of the problem formulation document.

Task 5: <u>Data Gathering: Literature Review</u>

The contractor shall conduct a thorough literature review to assess the availability of data to quantify the potential exposure doses for each identified exposure pathway in the carcass disposal process conceptual models for each phase of the project.

Deliverables: Literature Reviews

Performance Standard: The contractor shall provide the draft literature review and expert workshop report within 4 months after approval of the conceptual models document.

Task 6: Quantification of Potential Exposure Pathways and Relative Ranking of Disposal Options Final Report

The contractor shall compose a final report for the exposure assessment to include results of the previous tasks (final problem formulation, refined conceptual models, and gathered expert input and literature data). In the final report, the contractor shall also refine the conceptual models exposure pathways based on the available data from the literature and expert input to quantify potential exposures. For each identified disposal option, the potential exposures shall be quantified for each exposure pathways for each identified hazard. The contractor shall develop a relative ranking of the carcass disposal options and identify all assumptions, variabilities, and uncertainties. The final report shall also identify knowledge gaps where further study could help to minimize the uncertainty associated with the results of the exposure assessment.

Deliverables: Final Report

Performance Standard: The contractor shall provide the draft final report within 6 months after approval of the literature review and expert workshop report.

Task 7: Communications and Progress Reports

Bi-weekly conference calls shall be conducted between the WA-COR and the contractor to keep the project team updated on tasks progress and completion as well as any unanticipated issues.

Monthly Reports: Every month, the contractor shall submit reports detailing the overall project status, including a narrative description of the work, preliminary conclusions, and path forward. The monthly report shall provide a concise summary of significant issues, changes in project status, publications, presentations, patents, results of travel, completion of scheduled milestones, project delays and other accomplishments/issues during the reporting period. This report shall also include the financial status at the end of each month (funds received, commitments, obligations, and expenditures) with a graph of the actual and projected obligations and expenditures for the current fiscal year, and new digital pictures relevant to the project.

The contractor shall provide monthly a list of all documents prepared about work done under contract funding to include internal technical reports and presentations, external technical reports and presentations, and responses to requests, whether in written or electronic form, for information from external sources. Copies of such information shall be made available to the WA-COR on request within two weeks of the request. The contractor shall also submit combined technical and financial bi-weekly reports through email briefly and concisely updating task progress, changes in project status, significant issues, and financial status.

Outside Presentations of Project Research: Attendance at research meetings to present project results should be limited to the contractor project lead and technical staff on an as needed basis as deemed appropriate by prior consent of WA-COR. All documents or presentations associated with this project shall be cleared through WA-COR prior to submission to outside sources as described below. Travel costs associated with this project shall be approved by WA-COR prior to confirming and registering for meetings.

Reporting Requirements: All contractor generated documents and reports including task reports, interim reports, and task deliverable reports shall be considered draft upon first submission to WA-COR shall provide comments back to the contractor within 3 weeks of submission. The contractor shall provide a final version back to WA-COR with responses and dispositions of comments.

All references cited in submitted reports and deliverables to WA-COR shall be provided to WA-COR either as a pdf copy in electronic form on disk or hardcopy.

The contractor shall ensure that all documents prepared under this WA are technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors). All supporting information shall be referenced and made available if requested.

The contractor shall be responsible for information and data collection, storage, processing, validation, calculations, reporting, and delivery to WA-COR. The contractor shall provide document preparation and revision and ensure that the products are responsive, timely, and of high quality to meet the requirements of the Agency. All documents prepared under these tasks shall respond to the issues identified by WA-COR, and include supporting references and rationale for the recommendations and conclusions given.

All written information (reports, reviewer comments and meeting reports) shall be prepared using Microsoft Word format. Any spreadsheet or database data shall be in Microsoft Office format compatible with EPA software. The literature resources shall be provided in Adobe Acrobat format (i.e., pdf file) or paper hard copy. The contractor shall provide a CD containing all data and documentation along with three hard copies of the final task deliverable reports and one copy of any references cited in the documents. The documents shall be formatted in 12-point Times New Roman Font and 1-1/2 line spacing.

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Deliverables: Bi-weekly conference calls, monthly reports, and periodic meetings.

Performance Standard: The contractor shall participate in bi-weekly conference calls and meetings as needed and submit bi-weekly emails and monthly reports.

IV. DELIVERABLES AND QUALITY ASSURANCE SURVEILLANCE

Task	Deliverable Performance Standard		Monitoring Method	
2	Quality Assurance Project Plan (QAPP)	Contractor shall provide the completed QAPP within 30 days of award	WA-COR shall document whether receipt of QAPP is timely and acceptable, and provide technical revisions as required	
	Revised QAPP	Contractor shall revise QAPP if required and submit final QAPP no more than 30 days after receipt of revisions	WA-COR shall document receipt of revised QAPP, and ensure that is timely and technically acceptable	
3	Problem Formulation Document	Contractor shall provide the completed problem formulation document within 3 months after approval of the workplan and QAPP WA-COR shall document whether response to the workplan timely and acceptable, and provide technical revisions as required		
	Revised Problem Formulation Document Conceptual Models of Carcass Disposal Options Contractor shall revise problem formulation document if required and submit final document no more than 30 days after receipt of revisions Contractor shall provide the completed conceptual models within 3 months after approval of the problem formulation		WA-COR shall document receipt of revised problem formulation document, and ensure that is timely and technically acceptable	
4			WA-COR shall document the receipt of conceptual models, and ensure that they are timely and technically acceptable and provide technical comments as appropriate	
	Revised Conceptual Models of Carcass Disposal Options	Contractor shall revise conceptual models if required and submit final models no more than 30 days after receipt of revisions	WA-COR shall document the receipt of revised conceptual models, and ensure that they are timely and technically acceptable	
5	Literature Reviews Contractor shall provide the completed literature reviews within 4 months after approval of the conceptual models		WA-COR shall document the receipt of literature reviews, and ensure that they are timely and technically acceptable, and provide technical comments as appropriate	
	Revised Literature Reviews	Contractor shall revise literature reviews if required and submit reviews no more than 30 days after receipt of revisions	WA-COR shall document the receipt of revised literature reviews, and ensure that they are timely and technically acceptable	

6	Final Report	Contractor shall provide the draft Final Report within 6 months after approval of the literature reviews and expert workshop report	WA-COR shall document the receipt of final report, and ensure it is timely and technically acceptable, and provide technical comments as appropriate		
	Revised Final Report	Contractor shall revise final report if required and submit no more than 30 days after receipt of revisions	WA-COR shall document the receipt of revised report, and ensure it is timely and technically acceptable		
7	Bi-Weekly Conference Calls	Contractor shall participate in bi-weekly conference calls with the WA-COR briefly updating project progress	WA-COR shall participate in these calls to identify any issues to be addressed in the research or future reports		
	Monthly Reports	Contractor shall prepare monthly reports as specified in the statement of work	WA-COR shall document receipt of monthly reports and ensure that these are timely and acceptable		
	Meetings with WA-COR	Contractor shall have periodic meetings with the WA-COR as needed	WA-COR shall participate in these meetings and identify any issues to be addressed		

VI. INTELLECTUAL PROPERTY

All methods, models, and assays developed by the contractor and/or provided to the contractor under this WA are the intellectual property of the NHSRC and Department of Homeland Security (DHS). All data collected and analyzed under this WA are the intellectual property of the NHSRC and DHS.

Authorship on research presentations associated with this project including, but not limited to, abstracts, posters, PowerPoint presentations, and publications shall be agreed upon prior to submission for consideration by any external organization. Authorship should reflect 1) contribution through project conception and design, 2) data acquisition, 3) data interpretation and analysis, 4) presentation preparation.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- 1. Formulation of Agency policy
- 2. Selection of Agency priorities
- 3. Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of this WA, the contractor should immediately contact the EPA Contracting Officer.

The contractor shall also ensure that work under this WA does not contain any apparent or real personal or organizational conflicts of interest. The contractor shall certify that none exist with its workplan.

VIII. WORK ASSIGNMENT CONTRACT OFFICER REPRESENTATIVE (WA-COR) AND ALTERNATE WA-COR

WA-COR:

Sarah Taft, Ph.D.
U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT
National Homeland Security Research Center
26 W. Martin Luther King Drive (NG-16)
Cincinnati, OH 45268
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Taft.Sarah@epa.gov

Alternate WA-COR:

Paul Lemieux, Ph.D.
U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT
National Homeland Security Research Center
109 TW Alexander Drive (E343-06)
Research Triangle Park, NC 27711
Work 919/541-0962
Cell 513/300-9958
Lemieux.Paul@epa.gov

APPENDIX A

EPA's Quality System Website: http://www.epa.gov/quality

EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/ga_docs.html

EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

In accordance with EPA Order 5260.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approved the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions -

These requirements typically pertain to single project efforts. The five specifications are:

- (1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;
- (2) an organizational chart showing the position of the QA function;
- (3) delineation of the authority and responsibilities of the QA function;
- (4) the background and experience of the QA personnel who will be assigned to the project; and
- (5) the organization's general approach for accomplishing the QA specifications in the SOW.

NHSRC QA Requirements/Definitions List

Category Level Designations (determines the level of QA required):

Category I Project - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.
Category II Project - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.
Category III Project - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the NHSRC's QMP: QAPP requirements for the specific project type (see below).
Category IV Project - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the NHSRC's QMP QAPP requirements for the specific project type (see below).

Project Types:

These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where otherwise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to serve as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPPs must

n to applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the e of adequate quality and quantity to fit their intended purpose.
Applied Research Project - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.
Basic Research Project - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.
Design, Construction, and/or Operation of Environmental Technology Project - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-05.pdf . For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.
Geospatial Data Quality Assurance Project - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf .
Method Development Project - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.
Model Development Project - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling."
Sampling and Analysis Project - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.
Secondary Data Project - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.
Software Development and Data Management Project - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - Incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations

COR	Contracting Officer's Representative
NHSRC	National Homeland Security Research Center
NRMRL	National Risk Management Research Laboratory
QA ID	Quality Assurance Identification
QAPP	Quality Assurance Project Plan
QS	Quality System
TLP	Technical Lead Person
IAG	Interagency Agreement
QA	Quality Assurance
QAM	Quality Assurance Manager
QMP	Quality Management Plan
SOW	Statement of Work

CRADA Cooperative Research & Development Agreement

EPA			United		nental Protection a gton, DC 20460	:	Work Assignment Number 0-24					
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	(Signature) (Date)							FAX Number: 513-487-2107				

PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-24

TITLE: Exposure assessment of livestock carcass disposal options

Specify Section & Paragraph SOW: A2 Exposure Assessment Documents.

I. OBJECTIVES

The main objectives of this Work Assignment (WA) are to determine:

- Hazards associated with livestock carcass disposal options following a natural disaster, Foreign Animal Disease (FAD) outbreak, or other potential cause for massive carcass disposal of livestock
- Exposure pathways associated with each identified carcass disposal option
- Calculated exposures for each exposure pathway with sufficient data to quantify
- Levels of uncertainty in the calculated exposures
- Carcass disposal options that are the least likely to result in exposure impacts to additional livestock, human health, and/or the environment
- Knowledge gaps for further study to help minimize uncertainties in the assessment

II. BACKGROUND

The U.S. Environmental Protection Agency's (EPA's) National Homeland Security Research Center (NHSRC) was established to conduct research in support of indoor/outdoor decontamination and water security. Specifically, NHSRC is responsible for assessing potential exposures associated with the intentional or accidental release of hazardous and toxic materials including chemical, biological, and nuclear agents. NHSRC is currently developing tools, technologies, and methods to aid and support this effort. One of the highest priorities of NHSRC is the applications of risk assessment methodologies that can be utilized to support decision making regarding cleanup goals, treatment technology efficacies, detection limits, and waste management options during biological contamination incidents.

Under the National Response Framework, EPA is a support agency for federalized responses to Foreign Animal Disease (FAD) outbreaks, providing support to the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA/APHIS). One of the likely areas where EPA might provide support to USDA/APHIS is in helping to assure the proper disposal of animal carcasses following major event such as a natural disaster or FAD outbreak. Currently, there are several accepted carcass disposal options including rendering, composting, sanitary landfills, permitted incinerators, open burning, and unlined burial (Figure 1). Given the incident-specific nature of a massive carcass disposal response, there are knowledge gaps in comparing these disposal technologies from environmental, cost, human health, and animal health standpoints. Developing a risk-based methodology to allow decision makers to select the most appropriate carcass disposal technology for a given incident would significantly improve the Nation's preparedness.

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		Car	cass D	isposal C	Options	Process	ses		·
Rendering				transport to rendering		grind carcasses	cook	manage steam, tallow, and meal	
Sanitary Landfill	×		*	transport to landfill		bury carcasses	landfill	leachate, gas, and lids	Human, Ecological, and Livestock Health Risks
Permitted Incinerator	Load animal into truck	Cover truck	decon outside of truck	transport to incinerator	Inload truck	load animals into incinerator	process	manage air emissions and ash	and Livestoc
Composting	Load an	8	o uooep	transport to compost area	u n	build windrows	Mark to the State of the State	e finished npost	, Ecological,
Open Burning		•		transport to burn site		burn carcasses		leachate, d smoke	Human
Unlined Burial			€	transport to burial site		bury carcasses		methane eachate	

Figure 1. Potential carcass disposal option processes to evaluate for associated hazards and exposure pathways.

The following tasks cover the length of the project and are included here for reference; however, it is estimated that only Tasks 1-5 and 7 for Phase 1 will be completed during the base year of the contract. Please include only that work for purposes of the work plan cost estimate.

III. TASKS

Task 1: Workplan

The contractor shall generate a workplan describing how tasks 2-6 shall be performed. The workplan shall include the overall project purpose, scope, and approach. Each task shall be described in detail including the specifics of the personnel projected to complete each task indicating the level of expertise required, personnel labor hours, timelines to complete each task, projected costs of each task, equipment and supplies required, facilities to be used, specific standard operating procedures (SOPs) (or location of SOPs on-site if considered proprietary business information), standards and controls used for compliance with quality assurance, data

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analysis and calculations to be utilized, safety considerations, and the risks associated with each task along with proposed mitigations. The workplan shall outline the tasks and subtasks along with timelines projected for completion of each task and task inter-relationships.

Deliverables: Workplan and Project Management file

Task 2: Quality Assurance Project Plan (QAPP)

The contractor shall develop a Quality Assurance Project Plan (QAPP) to describe data quality objectives and data usage requirements for this effort. The contractor shall demonstrate in the QAPP how the organization shall plan, implement, and assess the effectiveness of its quality assurance and quality control procedures. The QAPP should incorporate a test plan to outline how the research shall be conducted and the measures taken to ensure data quality using the appropriate practices. This WA is a QA Category II Project and shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5" detailed in Appendix A. The contractor shall not perform work under Task 3-6 until the QAPP is reviewed and approved by the EPA WA-COR. The contractor may begin work on Tasks 1 and 2 upon receipt of this WA. The contractor is responsible for the quality of the work, data and/or measurements of any potential subcontractors. The process the contractor shall use for assessment of quality standards and measurements performed by any subcontractor shall be addressed in the QAPP.

The contractor shall provide QAPP document preparation and revision(s) as well as maintaining any additional quality assurance paperwork, including required SOPs or records of work performed. The contractor shall ensure that the products are responsive, timely, and of high quality to meet the requirements of the Agency. The contractor shall ensure that this documentation is maintained in an appropriate fashion, and make this documentation available for inspection by the EPA WA-COR, the EPA Quality Assurance Manager or others as designated by these individuals. All supporting documentation shall be referenced and attached.

Deliverable: QAPP

Performance Standard: The contractor shall provide the draft QAPP containing all required elements mentioned above within 30 days of award.

Task 3: Exposure Assessment Problem Formulation

The contractor shall draft the problem formulation document describing the purpose and scope of the exposure assessment by identifying a basic assessment framework (including the determination of boundaries of the assessment), necessary data or model inputs and outputs, and the key assumptions. The complexities and final scope of the exposure assessment including which identified hazards and disposal options to evaluate will be determined by the WA-COR and project team. The exposure assessments will most likely be completed in phases as follows:

- Phase 1. Comparison of carcass disposal options after natural disaster
- Phase 2. Comparison of carcass disposal options after FAD, Foot and Mouth Disease (FMD)
- Phase 3. Comparison of carcass disposal options after chemical exposure, Dioxin
- Phase 4. Comparison of carcass disposal options after radiological exposure
- Phase 5. Presentations of assessment results at series of expert workshops

The contractor shall estimate the cost broken down into each of these exposure assessment phases. The project team, WA-COR, and contractor will discuss options for the complete exposure assessment prior to the

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completion of the problem formulation document. The problem formulation document shall include but is not limited to the following sections:

- Statement of Purpose
- Questions to be Addressed
- Scope
 - o Hazard Identification and Screening
 - o Receptors (Livestock, human, and/or environment)
 - o Endpoints of Assessment
 - o Exposure Durations and Units of Exposure

Deliverable: Problem Formulation Document

Performance Standard: The contractor shall provide the draft problem formulation document within 3 months after approval of work plan and QAPP.

Task 4: Carcass Disposal Options Processes Conceptual Models

The contractor shall develop conceptual models for each of the identified carcass disposal options for each phase of the project. The conceptual models will qualitatively describe the disposal options processes to describe suspected sources, potential pathways of exposure, and potential receptors. The models shall concisely convey the underlying assumptions of the exposure assessment and how the exposure of receptors will be modeled to occur. The carcass disposal options conceptual models shall be developed based on available information regarding the potential fate, transport, and exposure route.

Deliverable: Conceptual Models Document

Performance Standard: The contractor shall provide the draft conceptual models document within 3 months after approval of the problem formulation document.

Task 5: Data Gathering: Literature Review

The contractor shall conduct a thorough literature review to assess the availability of data to quantify the potential exposure doses for each identified exposure pathway in the carcass disposal process conceptual models for each phase of the project.

Deliverables: Literature Reviews

Performance Standard: The contractor shall provide the draft literature review and expert workshop report within 4 months after approval of the conceptual models document.

Task 6: Quantification of Potential Exposure Pathways and Relative Ranking of Disposal Options Final Report

The contractor shall compose a final report for the exposure assessment to include results of the previous tasks (final problem formulation, refined conceptual models, and gathered expert input and literature data). In the final report, the contractor shall also refine the conceptual models exposure pathways based on the available data from the literature and expert input to quantify potential exposures. For each identified disposal option, the

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potential exposures shall be quantified for each exposure pathways for each identified hazard. The contractor shall develop a relative ranking of the carcass disposal options and identify all assumptions, variabilities, and uncertainties. The final report shall also identify knowledge gaps where further study could help to minimize the uncertainty associated with the results of the exposure assessment.

Deliverables: Final Report

Performance Standard: The contractor shall provide the draft final report within 6 months after approval of the literature review and expert workshop report.

Task 7: Communications and Progress Reports

Bi-weekly conference calls shall be conducted between the WA-COR and the contractor to keep the project team updated on tasks progress and completion as well as any unanticipated issues.

Monthly Reports: Every month, the contractor shall submit reports detailing the overall project status, including a narrative description of the work, preliminary conclusions, and path forward. The monthly report shall provide a concise summary of significant issues, changes in project status, publications, presentations, patents, results of travel, completion of scheduled milestones, project delays and other accomplishments/issues during the reporting period. This report shall also include the financial status at the end of each month (funds received, commitments, obligations, and expenditures) with a graph of the actual and projected obligations and expenditures for the current fiscal year, and new digital pictures relevant to the project.

The contractor shall provide monthly a list of all documents prepared about work done under contract funding to include internal technical reports and presentations, external technical reports and presentations, and responses to requests, whether in written or electronic form, for information from external sources. Copies of such information shall be made available to the WA-COR on request within two weeks of the request. The contractor shall also submit combined technical and financial bi-weekly reports through email briefly and concisely updating task progress, changes in project status, significant issues, and financial status.

Outside Presentations of Project Research: Attendance at research meetings to present project results should be limited to the contractor project lead and technical staff on an as needed basis as deemed appropriate by prior consent of WA-COR. All documents or presentations associated with this project shall be cleared through WA-COR prior to submission to outside sources as described below. Travel costs associated with this project shall be approved by WA-COR prior to confirming and registering for meetings.

Reporting Requirements: All contractor generated documents and reports including task reports, interim reports, and task deliverable reports shall be considered draft upon first submission to WA-COR. WA-COR shall provide comments back to the contractor within 3 weeks of submission. The contractor shall provide a final version back to WA-COR with responses and dispositions of comments.

All references cited in submitted reports and deliverables to WA-COR shall be provided to WA-COR either as a pdf copy in electronic form on disk or hardcopy.

The contractor shall ensure that all documents prepared under this WA are technically accurate, defensible, free of errors (e.g., data entry, methodology), and editorially correct (e.g., free of typographic and grammatical errors). All supporting information shall be referenced and made available if requested.

The contractor shall be responsible for information and data collection, storage, processing, validation, calculations, reporting, and delivery to WA-COR. The contractor shall provide document preparation and revision and ensure that the products are responsive, timely, and of high quality to meet the requirements of the Agency. All documents prepared under these tasks shall respond to the issues identified by WA-COR, and include supporting references and rationale for the recommendations and conclusions given.

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All written information (reports, reviewer comments and meeting reports) shall be prepared using Microsoft Word format. Any spreadsheet or database data shall be in Microsoft Office format compatible with EPA software. The literature resources shall be provided in Adobe Acrobat format (i.e., pdf file) or paper hard copy. The contractor shall provide a CD containing all data and documentation along with three hard copies of the final task deliverable reports and one copy of any references cited in the documents. The documents shall be formatted in 12-point Times New Roman Font and 1-1/2 line spacing.

Deliverables: Bi-weekly conference calls, monthly reports, and periodic meetings.

Performance Standard: The contractor shall participate in bi-weekly conference calls and meetings as needed and submit bi-weekly emails and monthly reports.

IV. DELIVERABLES AND QUALITY ASSURANCE SURVEILLANCE

Task	Deliverable	Performance Standard	Monitoring Method
2	Quality Assurance Project Plan (QAPP)	Contractor shall provide the completed QAPP within 30 days of award	WA-COR shall document whether receipt of QAPP is timely and acceptable, and provide technical revisions as required
	Revised QAPP	Contractor shall revise QAPP if required and submit final QAPP no more than 30 days after receipt of revisions	WA-COR shall document receipt of revised QAPP, and ensure that is timely and technically acceptable
3	Problem Formulation Document	Contractor shall provide the completed problem formulation document within 3 months after approval of the workplan and QAPP	WA-COR shall document whether receipt of problem formulation document is timely and acceptable, and provide technical revisions as required
	Revised Problem Formulation Document	Contractor shall revise problem formulation document if required and submit final document no more than 30 days after receipt of revisions	WA-COR shall document receipt of revised problem formulation document, and ensure that is timely and technically acceptable
4	Conceptual Models of Carcass Disposal Options	Contractor shall provide the completed conceptual models within 3 months after approval of the problem formulation	WA-COR shall document the receipt of conceptual models, and ensure that they are timely and technically acceptable and provide technical comments as appropriate
	Revised Conceptual Models of Carcass Disposal Options	Contractor shall revise conceptual models if required and submit final models no more than 30 days after receipt of revisions	WA-COR shall document the receipt of revised conceptual models, and ensure that they are timely and technically acceptable
5	Literature Reviews	Contractor shall provide the completed literature reviews within 4 months after approval of the conceptual models	WA-COR shall document the receipt of literature reviews, and ensure that they are timely and technically acceptable, and

			provide technical comments as appropriate
	Revised Literature Reviews	Contractor shall revise literature reviews if required and submit reviews no more than 30 days after receipt of revisions	WA-COR shall document the receipt of revised literature reviews, and ensure that they are timely and technically acceptable
6	Final Report	Contractor shall provide the draft Final Report within 6 months after approval of the literature reviews and expert workshop report	WA-COR shall document the receipt of final report, and ensure it is timely and technically acceptable, and provide technical comments as appropriate
	Revised Final Report	Contractor shall revise final report if required and submit no more than 30 days after receipt of revisions	WA-COR shall document the receipt of revised report, and ensure it is timely and technically acceptable
7	Bi-Weekly Conference Calls	Contractor shall participate in bi-weekly conference calls with the WA-COR briefly updating project progress	WA-COR shall participate in these calls to identify any issues to be addressed in the research or future reports
	Monthly Reports	Contractor shall prepare monthly reports as specified in the statement of work	WA-COR shall document receipt of monthly reports and ensure that these are timely and acceptable
	Meetings with WA-COR	Contractor shall have periodic meetings with the WA-COR as needed	WA-COR shall participate in these meetings and identify any issues to be addressed

VI. INTELLECTUAL PROPERTY

All methods, models, and assays developed by the contractor and/or provided to the contractor under this WA are the intellectual property of the NHSRC and Department of Homeland Security (DHS). All data collected and analyzed under this WA are the intellectual property of the NHSRC and DHS.

Authorship on research presentations associated with this project including, but not limited to, abstracts, posters, PowerPoint presentations, and publications shall be agreed upon prior to submission for consideration by any external organization. Authorship should reflect 1) contribution through project conception and design, 2) data acquisition, 3) data interpretation and analysis, 4) presentation preparation.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- 1. Formulation of Agency policy
- 2. Selection of Agency priorities
- 3. Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of this WA, the contractor should immediately contact the EPA Contracting Officer.

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The contractor shall also ensure that work under this WA does not contain any apparent or real personal or organizational conflicts of interest. The contractor shall certify that none exist with its workplan.

VIII. WORK ASSIGNMENT CONTRACT OFFICER REPRESENTATIVE (WA-COR) AND ALTERNATE WA-COR

WA-COR:

Sarah Taft, Ph.D.
U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT
National Homeland Security Research Center
26 W. Martin Luther King Drive (NG-16)
Cincinnati, OH 45268
Work 513/569-7037
Cell 513/288-5460
Taft.Sarah@epa.gov

Alternate WA-COR:

Paul Lemieux, Ph.D.
U.S. EPA OFFICE OF RESEARCH AND DEVELOPMENT
National Homeland Security Research Center
109 TW Alexander Drive (E343-06)
Research Triangle Park, NC 27711
Work 919/541-0962
Cell 513/300-9958
Lemieux.Paul@epa.gov

APPENDIX A

EPA's Quality System Website: http://www.epa.gov/quality

EPA's Requirements and Guidance Documents: http://www.epa.gov/quality/qa_docs.html EPA's Quality System Website: http://www.epa.gov/quality/qs-docs/r5-final.pdf

In accordance with EPA Order 5260.1 A2, conformance to ANSI/ASQC E4 must be demonstrated by submitting the quality documentation described herein. All Quality documentation shall be submitted to the Government for review. The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, it must be revised to address all comments and shall be resubmitted to the Government for approval. Work involving environmental data collection, generation, use, or reporting shall not commence until the Government has approved the quality documentation. The Quality Assurance Project Plan (QAPP) shall be submitted to the Government at least thirty (30) days prior to the beginning of any environmental data gathering or generation activity in order to allow sufficient time for review and revisions to be completed. After the Government has approved the quality documentation, the Contractor shall also implement it as written and approved by the Government.

NHSRC's Quality System Specifications for Extramural Actions -

These requirements typically pertain to single project efforts. The five specifications are:

- (1) a description of the organization's Quality System (QS) and information regarding how this QS is documented, communicated and implemented;
- (2) an organizational chart showing the position of the QA function;
- (3) delineation of the authority and responsibilities of the QA function;
- (4) the background and experience of the QA personnel who will be assigned to the project; and
- (5) the organization's general approach for accomplishing the QA specifications in the SOW.

NHSRC QA Requirements/Definitions List

Category Level Designations (determines the level of QA required):

	Category I Project - applicable to studies performed to generate data used for enforcement activities, litigation, or research project involving human subjects. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5.
П	Category II Project - applicable to studies performed to generate data used in support of the development of environmental regulations or standards. The QAPP shall address all elements listed in "EPA Requirements for QA Project Plans, EPA QA/R-5

	Category III Project - applicable to projects involving applied research or technology evaluations. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the NHSRC's QMP: QAPP requirements for the specific project type (see below).
	Category IV Project - applicable to projects involving basic research or preliminary data gathering activities. The QAPP shall address the applicable sections of "EPA Requirements for QA Project Plans, EPA QA/R-5 as outlined in the NHSRC's QMP QAPP requirements for the specific project type (see below). Project Types:
otherw to serv conform	These outlines of NHSRC's QAPP Requirements for various project types, from Appendix B of the NHSRC QMP (except where rise noted), are condensed from typically applicable sections of R-5 (EPA Requirements for QA Project Plans) and are intended to as a starting point when preparing a QAPP. These lists and their format may not fit every research scenario and QAPPs must not applicable sections of R-5 in a way that fully describes the research plan and appropriate QA and QC measures to ensure that the e of adequate quality and quantity to fit their intended purpose.
	Applied Research Project - pertains to a study performed to generate data to demonstrate the performance of accepted processes or technologies under defined conditions. These studies are often pilot- or field-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Applied Research Projects" from Appendix B of the NHSRC QMP.
	Basic Research Project - pertains to a study performed to generate data used to evaluate unproven theories, processes, or technologies. These studies are often bench-scale. The QAPP shall address all requirements listed in "QAPP Requirements for Basic Research Projects" from Appendix B of the NHSRC QMP.
	Design, Construction, and/or Operation of Environmental Technology Project - pertains to environmental technology designed, constructed and/or operated by and/or for EPA. The QAPP shall address requirements in the EPA Quality System document "Guidance on Quality Assurance for Environmental Technology Design, Construction, and Operation" G-11, at http://www.epa.gov/quality/QS-docs/g11-final-05.pdf . For additional information, you may refer to Part C of "Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology," ANSI/ASQC E4-1994, American Society for Quality Control, Milwaukee, WI, January 1995.
	Geospatial Data Quality Assurance Project - pertains to data collection; data processing and analysis; and data validation of geospatial applications. The QAPP shall address requirements in the EPA Quality System document "Guidance for Geospatial Data Quality Assurance Project Plans" G-5S at http://www.epa.gov/quality/QS-docs/g5g-final-05.pdf .
	Method Development Project - pertains to situations where there is no existing standard method, or a standard method needs to be significantly modified for a specific application. The QAPP shall address all requirements listed in "QAPP Requirements for Method Development Projects" from Appendix B of the NHSRC QMP.
	Model Development Project - includes all types of mathematical models including static, dynamic, deterministic, stochastic, mechanistic, empirical, etc. The QAPP shall address requirements in the EPA Quality System document "Guidance for Quality Assurance Project Plans for Modeling."
	Sampling and Analysis Project - pertains to the collection and analysis of samples with no objectives other than to provide characterization or monitoring information. The QAPP shall address all requirements listed in "QAPP Requirements for Sampling and Analysis Projects" from Appendix B of the NHSRC QMP.
	Secondary Data Project - pertains to environmental data collected from other sources, by or for EPA, that are used for purposes other than those originally intended. Sources may include: literature, industry surveys, compilations from computerized databases and information systems, and computerized or mathematical models of environmental processes. The QAPP shall address all requirements listed in "QAPP Requirements for Secondary Data Projects" from Appendix B of the NHSRC QMP.
	Software Development and Data Management Project - pertains to software development, software/hardware systems development, database design and maintenance, data validation and verification systems. The QAPP shall address all requirements listed in "QAPP Requirements for Software Development Projects" from Appendix B of the NHSRC QMP.
	•

Definitions:

Environmental Data - These are any measurement or information that describe environmental processes, location, or conditions; ecological or health effects directly from measurements, produced from software and models, and compiled from other sources such as data bases or the literature. For EPA, environmental data include information collected directly from measurements, produced from software and models, and compiled from other sources such as data bases or literature.

Incremental Funding - Incremental funding is partial funding, no new work.

Quality Assurance (QA) - Quality assurance is a system of management activities to ensure that a process, item, or service is of the type and quality needed by the customer. It deals with setting policy and running an administrative system of management controls that cover planning, implementation, and review of data collection activities and the use of data in decision making. Quality assurance is just one part of a quality system.

Quality Assurance Project Plan (QAPP) - A QAPP is a document that describes the necessary quality assurance, quality control, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria. A QAPP documents project-specific information.

Quality Control (QC) - Quality control is a technical function that includes all the scientific precautions, such as calibrations and duplications, which are needed to acquire data of known and adequate quality.

Quality Management Plan (QMP) - A QMP is a document that describes an organization's/program's quality system in terms of the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, documenting, and assessing all activities conducted. A QMP documents the overall organization/program, and is primarily applicable to multi-year, multi-project efforts. An organization's/program's QMP shall address all elements listed in the "Requirements for Quality Management Plans" in Appendix B of the NHSRC QMP.

Quality System - A quality system is the means by which an organization manages its quality aspects in a systematic, organized manner and provides a framework for planning, implementing, and assessing work performed by an organization and for carrying out required quality assurance and quality control activities.

R-2. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r2-final.pdf.

R-5. EPA Requirements for Quality Management Plans (EPA/240/B-01/002) March, 2001 http://www.epa.gov/quality/QS-docs/r5-final.pdf.

Substantive Change - Substantive change is any change in an activity that may alter the quality of data being used, generated, or gathered.

Technical Lead Person (TLP) - This person is technically responsible for the project. For extramural contract work, the TLP is typically the contracting officer's representative (COR). For intramural work, the TLP is typically the Principal Investigator.

Abbreviations

COR	Contracting Officer's Representative
L.C.IR	Contracting Unicer's Representative

NHSRC National Homeland Security Research Center NRMRL National Risk Management Research Laboratory

QA ID Quality Assurance Identification QAPP Quality Assurance Project Plan

QS Quality System

TLP Technical Lead Person
IAG Interagency Agreement
QA Quality Assurance
QAM Quality Assurance Manager
QMP Quality Management Plan

SOW Statement of Work

CRADA Cooperative Research & Development Agreement

	United States Environmenta	Protection Agency	Work Assignment Number				
EDA	Washington,	1-1	0-24				
EPA	Work Assi	gnment	Other X Amendment Number:				
		_	000001				
Contract Number	Contract Period 11/01/	2013 To 10/31/2	2014 Title of Work Assignment/SF Site Name				
EP-C-14-001	Base X Opti	on Period Number	Livestock Carcass Disposal				
Contractor	-	Specify Section and par	ragraph of Contract SOW				
ICF INCORPORATED, L.L.C.							
Purpose: Work Assignment	Ŭ w∘	rk Assignment Close-Out	Period of Performance				
X Work Assignment Ame	endment Inci	remental Funding					
X Work Plan Approval			From 02/07/2014 To 10/31/2014				
Comments:							
Superfund	Accountin	ng and Appropriations Data	X Non-Superfund				
	Note: To report additional accounti		ZZ New Superior				
SFO (Max 2)		- 3					
DCN Budget/FY Approp (Max 6) (Max 4) Code (I		gram Element Object Class (Max 9) (Max 4)	Amount (Dollars) (Cents) Site/Project Cost Org/Code (Max 8) (Max 7)				
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2							
3							
4							
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Contract Period:		ed Work Assignment Ceiling	- in				
11/01/2013 To 10/31/2014	Cost/Fee: \$0.00		LOE: 0				
This Action:	\$143,986.00		1,244				
Total:	\$143,986.00		1,244				
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PERFORMANCE WORK STATEMENT

Contract Number: EP-C-14-001 Work Assignment Number 0-25

Title: Risk Assessment Forum Uncertainty and Variability Current Practices Report

SOW Section & Paragraph: A. Assessment Issues and Documents

PERIOD OF PERFORMANCE:

Award - October 31, 2014

A. BACKGROUND

An overarching priority for EPA is to enhance the characterization of uncertainty and variability in Agency risk assessments that inform risk management decisions. A recurring recommendation of many panels internally and externally to the Agency, has been to develop processes to evaluate, address, and communicate uncertainty and variability in key computational steps of risk assessment. Current practice at EPA, supported by numerous guidance documents/policies, tools, and methods, varies from simple to more complex analyses. To incorporate recent advances in uncertainty and variability analysis and to facilitate consensus on key aspects of such analyses in light of current methods and approaches, updated or new Agency-wide materials may be needed. The development of these Agency materials may vary from rather quick dissemination/training of existing tools and practices to more complex efforts to develop consensus methods. Before an efficient and directed plan for providing the necessary tools, guidance, and methods for uncertainty and variability analyses can be pursued, consideration of the various approaches currently employed for different Agency risk assessment needs and a thorough inventory and evaluation of currently available tools is needed.

The Risk Assessment Forum (RAF) Uncertainty and Variability Technical Panel was formed to address the need to advance the science of uncertainty and variability, with the immediate purpose to develop a plan for addressing Agency needs in this area. Accordingly, it is expected that this work assignment will consider current practices and needs with regard to the various computational risk assessment steps, including characterization of source, emissions, environmental fate, exposure, dose-response assessment, and risk characterization. The Technical Panel is tasked with preparing a Current Practices Report and a Resource Inventory (e.g., policies, guidance, tools, etc.) from across the Agency (i.e. program offices and regions) that will provide the basis for discussions at an Agency-wide Colloquium. The Colloquium will allow the Technical Panel to obtain feedback and input on the Current Practices Report and Resource Inventory as to their completeness and accuracy and subsequent identification of next steps. Where feasible, the Colloquium discussions will cover the preliminary identification of gaps/needs and prioritization of next steps. The final anticipated products of this Panel are a Gap Analysis Report (to identify guidance/policy, tools/methods, and training not currently available that might improve and facilitate such analyses) and a prioritized Action Plan to address identified gaps).

B. PURPOSE

This work assignment (WA) directs the Contractor to support the Technical Panel in the preparation of the Current Practices Report and Resource Inventory and the coordination and conduct of the Agency-wide Colloquium. The Panel has already undertaken a data collection effort where Panel members have collected information on how the various programs within EPA characterize uncertainty and variability and how that information is used (or not) to support decisions. The Contractor will have access to this information and other

information as needed consistent with the Confidentiality Clause provided in Section H.

This WA will serve as a generic task list with the intention that technical direction will be issued for each specific task. The technical direction will contain instructions specific to the initiative.

C. KNOWLEDGE AND SKILLS REQUIRED

The Contractor shall provide technical support to the RAF Technical Panel in developing a Current Practices Report and Resource Inventory related to how uncertainty and variability are addressed and considered within various programs at EPA and other similar regulatory agencies. The Contractor will also be required to provide support to the Panel to organize and carry out a virtual Agency-wide Colloquium to discuss these products.

To support the development of the two stated products, the tasks require expert personnel with experience in risk assessment, especially in uncertainty and variability, having the knowledge and ability to identify, evaluate, and summarize current practices, best practices, and the quality and relevance of existing resources (e.g. policies/guidance, regulatory/statutory foundation, and tools/methods). They must also be capable of presenting highly technical information in a manner that is easily understood by individuals from a broad range of disciplines. To support the organization and conduct of the Agency-wide Colloquium, the tasks require expert personnel in all aspects associated with organizing such large scale events.

STATEMENT OF WORK- Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 1. Summarize the information from the data call.

The Contractor shall review the data submitted by the Technical Panel to describe how uncertainty and variability are captured within each of the EPA program offices and regions. This information has been submitted in a variety of formats, some have been submitted via the form of a spreadsheet, while others have been prepared and submitted as stand-alone documents. The Contractor will review the information provided and propose a minimum of three (3) options for a format to organize the collection of information. Within one (1) week of receiving the technical direction, the Contractor shall submit proposed formats to the COR. Within one (1) week of proposal submissions, the Contractor shall convene a conference call with the COR, Technical Panel members, and appropriate contractor staff to determine the final format of data call information. The format and organization of the data call information will be agreed upon by the COR, Technical Panel members, and appropriate contractor staff. Within three (3) weeks of the conference call, the Contractor shall organize the data call information into the agreed upon format and create a summary of the data. The Contractor shall create a summary including commonalities and differences in risk assessment uncertainty and variability practices between programs. The purpose of the summary is to highlight overlapping practices, differences in practices, and best practices. The summary will provide the foundation for the Current Practices Report (Task 3).

Task 2. Outline practices of other groups and agencies addressing uncertainty and variability in their risk assessments to support risk management decisions.

The Contractor shall compile a bibliographic list of agencies that perform risk assessment which are used to

support their decisions and associated guidance and policies. Within one (1) week of receiving the technical directive, the Contractor shall submit the list to the EPA WA-COR with copies as needed for Technical Panel members, and appropriate contractor staff who shall review and approve the list. Agencies shall include, but are not limited to, DOE, FDA, WHO, NASA, and EU. Upon receiving approval from the COR regarding which agencies should be addressed (no more than 8 agencies are anticipated to be selected), the Contractor shall conduct a review of how uncertainty and variability is addressed within these agencies which conduct risk assessment to support their decisions. Within three (3) weeks of receiving approval, the Contractor shall perform a review of agency risk assessment uncertainty and variability practices. The review shall be limited to formal guidance, policy, and tools for the agencies. This review shall not be a general literature review. The review shall be short in length (no more than 10 pages per agency) and may be partially or wholly comprised of an annotated bibliography and links to specific references. The review shall summarize practices of agency programs including policy guidance, regulatory foundations, statutory foundations, tools and methods, and case studies. This task can be performed concurrently with Task 1.

Task 3. Develop an uncertainty and variability Current Practices Report.

The uncertainty and variability Current Practices Report shall be written based on the data call summary (Task 1) as well as integration of formal guidance of other regulatory agencies where applicable (Task 2). The Current Practices Report shall be used to facilitate discussion of uncertainty and variability practices at the Colloquium (see Task 5). The Contractor shall first prepare an outline and draft summary of the Current Practices Report within one (1) week of the technical directive. Concurrent with the outline and draft summary they shall propose alternative approaches to presenting the information in the report (e.g., charts, graphs, and matrices) that shall be approved by the COR within one (1) week of submission of the proposal. The Contractor shall prepare a draft Current Practices Report by May 30, 2014. The draft report shall highlight the commonalities, differences, and best practices among programs and regions within EPA and other agencies. The information should be presented separately for EPA and the other federal agencies with a summary of similarities and differences across both. The report shall incorporate results of the agency practices review and data call summary, and propose areas that need attention and/or discussion among Colloquium participants. The contractor shall develop an annotated bibliography with the Current Practices Report. The Contractor shall convene four (4) conference calls in May and June of 2014 with the COR, Technical Panel members, and appropriate contractor staff to discuss revisions to the draft report. The Contractor shall deliver a final report on July 1, 2014.

The Contractor shall add as a header—"Pre-decisional materials- Deliberative - Do not cite or quote" (or other appropriate language) to all drafts materials prepared.

Task 4. Create an inventory of resources.

Within one (1) week of the technical directive, the Contractor shall submit a proposal for managing and presenting an inventory of Agency resources related to uncertainty and variability to the COR, Technical Panel members, and appropriate contractor staff. The Contractor can consider any means which are appropriate (e.g., web-based, spreadsheets, etc). Within one (1) week of proposal submission, the COR and Technical Panel shall review and approve the format for the inventory. The Contractor shall convene a conference call with the COR, Technical Panel members, and appropriate contractor staff to discuss revisions to the format. Within two (2) weeks of an approved proposal, the Contractor shall collect and organize materials and submit a final inventory of resources concurrent with the final Current Practices Report (Task 3). The inventory shall summarize information and resources provided in the data call (Task 1) or follow-up with Technical Panel members, and include resources from other sources and agencies (Task 2), including summaries of programs and materials.

Task 5. Manage uncertainty and variability colloquium and provide logistical support

The Contractor shall be responsible for the following logistical support of the uncertainty and variability Colloquium:

- Meeting organization
- Creation and distribution of the Colloquium announcement
- Preparation and distribution of the agenda, background information, reports, attendance lists, and presentations.
- Take notes and summarize the Colloquium preparation.
- Take notes and summarize the Colloquium proceedings.
- Facilitate discussions at the Colloquium.
- Solicit the participation of experts (3 people from inside and outside the EPA)
- Coordinate travel support for outside participants.
- Facilitate break out groups.
- Provide technical support.

The Colloquium will be a virtual workshop. The Contractor shall provide technical and computer support for the virtual workshop. A proposal of virtual workshop logistics shall be presented to the COR, Technical Panel members, and appropriate contractor staff by June 2014. The primary site of the workshop will be Washington, D.C. with remote locations at Research Triangle Park, Cincinnati, and EPA regional offices. The Contractor shall facilitate attendance and registration of the Colloquium, coordinate with EPA technical support to manage offsite locations, and manage the recording of the Colloquium at the primary site.

D. SCHEDULE AND DELIVERABLES

Product	Due Date
Task 1. Summarize the information from the data call	a. 1 week after scoping
a. Submit memo proposing options for format to organize the	meeting for proposal
information	with COR, PO, and
b. Prepare draft data summary	Contractor
c. Final data summary	b. 2 weeks after receiving
	format approval
	c. 3 weeks after review of
	draft
Task 2. Outline practices of other groups and agencies addressing	a. 1 week after receiving
uncertainty and variability in risk assessment to support decisions.	technical directive
a. Submit list of other agencies who use risk assessment to support	b. 2 weeks after receiving
decisions	approval of agency list
b. Submit draft summary of other agency practices	c. 1 week after receiving
c. Final Summary	comments on draft
Task 3. Current Practices Report:	a. 1 week after receiving
a. Submit draft outline and presentation options	comments on Task 1 and
b. Submit draft report	2 drafts
c. Submit final report	b. May 30, 2014
c. Subilit final report	c. July 1, 2014
Task 4. Inventory of Resources	a. 1 week after the scoping
a. Submit proposal for how to manage and present inventory of	meeting with COR, PO,
resources	and Contractor
b. Draft resource inventory	b. May 30, 2014
c. Final resource inventory	c. July 1, 2014
Task 5. Workshop logistical support	TBD

E. ACCEPTANCE CRITERIA

Final products shall be produced by the Contractor upon the EPA WA COR's approval through written, technical direction. The Contractor shall provide all materials written as part of these tasks to the EPA WA COR, as per work assignment, in electronic format. Electronic versions shall be in MS Office, PowerPoint 2007, and Excel 2007 computer format unless otherwise stipulated.

F. QUALITY ASSURANCE REQUIREMENTS

Included in the technical memos should be an assessment of the quality of the data supporting the goals of the project. The Contractor shall assess any limitations associated with the data and analytical approaches used and how these may impact their use relative to this project's objectives.

G. MANAGEMENT CONTROLS

Periodic meetings between the EPA and the Contractor WA managers are required to discuss any questions that may arise during performance or completion of this WA. At the EPA WA COR's discretion, these meetings may occur via teleconference or video conferences. The Contractor shall document these meetings and submit

copies of this correspondence to the EPA WA COR.

The EPA WA COR may identify one or more EPA technical representatives for this WA. Interaction between the Contractor and any EPA technical representative(s) designated by the EPA WA COR is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this WA. Per the technical direction clause EPAAR 1552.237-71 of the contract, the EPA PO COR and the EPA WA COR or alternate EPA WA COR are the only representatives of the CO authorized to provide technical direction.

Per the technical direction clause, the CO and PO will be provided with copies of all technical direction.

H. CONFIDENTIALITY

Some of the information to be edited under this task may be internal information that is not ready for public distribution. The Contractor shall not discuss the contents of the document with anyone not specified as a participant in the document review process or its preparation.

Work Assignment COR:

Julie Fitzpatrick Office of Science Advisor U.S. EPA (8105-R) 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460 Telephone: (202) 564-4212 Fax: (202) 564-2070

Alternate Work Assignment COR:

Lawrence Martin
Office of the Science Advisor
U.S. EPA (8105-R)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Telephone: (202) 564-6497
Fax: (202) 564-2070

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-26

TITLE: Board of Scientific Counselors (BOSC) Meeting / Conference Support

Specify Section & Paragraph SOW: A. Assessment Issues and Documents E. Risk Assessment Support

PERIOD OF PERFORMANCE: CO award to 10/31/14

1. BACKGROUND

The primary functions of the BOSC include evaluating ORD's science and engineering research programs, laboratories, and research-management practices, and recommending actions to improve their quality and/or strengthen their relevance to the mission of the EPA. For more information on the BOSC, go to http://epa.gov/osp/bosc/.

2. PURPOSE

The purpose of this Work Assignment is to provide: a full range of administrative and logistical support services for the conduct of Federal Advisory Committee meetings, conferences and/or teleconferences related to the Charter of the Office of Research and Development's Board of Scientific Counselors (BOSC); administrative activities required for reports prepared by the BOSC Executive Committee or it's Subcommittees; and the full range of administrative support services for assimilating materials collected from extensive candidate searches conducted for either the Executive Committee, or existing or proposed Subcommittees.

The contractor's activities will not require special expertise in matters of science discussed by the Board, but the contractor should possess the practical knowledge, experience, and skills commonly used in facilitating high-level policy meetings.

Meetings of the BOSC Executive Committee and Subcommittees will generally be held on-site at US EPA (either Headquarters or a Laboratory/Center, as appropriate), if space is available, with the approval of the Designated Federal Officer (DFO). Under this work assignment, it is anticipated that contractor support shall be required for approximately four Executive Committee meetings (at least 3 are expected to be face-to-face meetings); approximately 5 face-to-face program review subcommittee meetings. In addition, contractor support shall be needed for approximately 17 conference calls (expected to be 2-3 hour calls) in support of the executive committee and subcommittee meetings. The EPA WAM will provide the meeting dates via written technical direction.

It is anticipated that approximately 10 reports shall be generated by the BOSC during the timeframe of this work assignment, and that candidate searches requiring contractor support may occur no more than 2 times per year.

3. STATEMENT OF WORK

This Statement of Work describes EPA's requirements regarding services to be rendered by the contractor for BOSC meeting and conference support. The contractor shall provide the necessary personnel and resources in the following four areas for the BOSC:

- 1. Pre-meeting communication and logistical support.
- 2. On-site technical support during meetings/teleconferences.
- 3. Prepare summary minutes of meetings/teleconferences.
- 4. Word processing for reports.

Task 1. Pre-meeting communication and logistical support

As requested by the EPA WAM, the contractor shall prepare a BOSC member's background binder for the list of invitees provided by the EPA WAM, to include agenda, minutes of last meeting (if appropriate), other background/logistical material needed for the meeting/teleconference. Via written technical direction, the meeting/teleconference dates will be provided by the EPA WAM. The contractor shall prepare a mail merge file and address labels for the list of members and invitees. All correspondence shall be transmitted under the Designated Federal Officer's name. It is anticipated that there will be approximately 30 participants for each Executive Committee meeting, and approximately 30-100 participants for each Subcommittee face-to-face meeting.

The contractor shall obtain meeting space facilities when government owned facilities are not available, as determined by the EPA WAM (this includes negotiation with hotels or other entities to obtain meeting space, as well as reservations (room blocks) for lodging that fall within U.S. Government per-diem rates and meet GovTrip lodging requirements).

Task 2. On-site technical support during meetings/teleconferences

The contractor shall provide recorders to take minutes at each meeting/teleconference. The contractor shall ensure that all equipment needed at the meeting is available, to include microphone equipment, laptop computers, etc., as needed and specified by the EPA WAM.

The contractor shall provide a registration table each day of the meeting and shall provide table tents and name badges of participants. The contractor shall also photocopy additional sets of handouts and materials as may be required during the course of the meeting, on a fast turnaround basis, as requested by the EPA WAM.

The contractor shall deliver to the EPA WAM any materials not distributed at the meeting or materials left behind by BOSC members within two working days after the meeting.

Task 3. Prepare summary minutes of meetings/teleconferences

The contractor shall prepare and submit to the EPA WAM draft minutes of the meetings/teleconferences within 15 working days of the end of each meeting/teleconference. The contractor shall incorporate comments and changes to the minutes per written technical direction by the EPA WAM and submit final minutes within 5 working days of receiving EPA comments. The draft and final minutes shall be provided in electronic format (Word is the Agency standard software).

Task 4. Word Processing for Reports

The contractor shall provide word processing support for any reports prepared by the BOSC Executive Committee or its Subcommittees. The contractor shall not be involved in developing the technical content of the report, and shall not provide any scientific technical expertise. The contractor shall only provide word processing services to compile, format, edit (based on Executive Committee and Subcommittee member input, plus any factual changes requested by ORD and approved by the Executive Committee), and finalize reports prepared by the Executive Committee or its Subcommittees.

The contractor shall compile/format/edit and submit draft Executive Committee/ Subcommittee reports to the EPA WAM within 15 working days after receiving report content. The contractor shall incorporate comments and changes to the reports and submit final reports to the EPA WAM within 5 working days of receiving comments. The draft and final reports shall be provided in electronic format (Word is the Agency standard software).

Due Date

5. SCHEDULE OF DELIVERABLES

Product

Kickoff	3 days after receipt of work assignment
Logistical Arrangements of Meeting	30 working days prior to meeting
Draft Minutes of Meeting (To EPA WAM)	15 working days after completion of meeting
Final Minutes of Meeting (to EPA WAM)	5 working days after receipt of comments from EPA WAM
Draft Exec Committee/Sub- committee reports (to	15 working days after receipt of report EPA WAM) content from EPA WAM

6. SPECIAL CONDITIONS

Final Exec Committee/Sub-

committee reports (to

Final products shall be produced by the Contractor upon EPA WAM's approval through written technical direction. The Contractor shall provide all materials written under these tasks to the EPA WAM, as per work assignment, in electronic form. Electronic version shall be compatible with the ORD's computer systems and software, (e.g., Microsoft Word).

5 working days after receipt of comments

EPA WAM) from EPA WAM

Separate from the Monthly Progress Report, the contractor costs shall be provided to the EPA WAM on a monthly basis, and shall be compiled separately for the Executive Committee and each Subcommittee. EPA is required to annually input cost information for each committee or subcommittee into a government-wide

database, and EPA will not be able to comply with this federal requirement unless contractor costs are tracked and reported to EPA by each committee/subcommittee.

7. CONFIDENTIALITY

Some of the work assigned under these tasks may be to draft, edit, and review program and sensitive organizational information that will not be ready for broad or public distribution. The contractor shall not discuss the contents of any document with anyone not specified as a participant in the documents review process or its preparation. The EPA WAM will supply the contractor with a list of individuals involved with any documents under these tasks.

8. MANAGEMENT CONTROLS

Periodic meetings between the EPA and contractor work assignment managers are encouraged to discuss any questions that may arise during performance or completion of this work assignment. At the EPA WAM's discretion, these meetings may occur via teleconference or video conferences. The contractor shall document these meetings and submit copies of this correspondence to the EPA WAM.

The EPA WAM may identify one or more EPA technical representatives for this work assignment. Interaction between the contractor and any EPA technical representative(s) designated by the EPA WAM is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this work assignment. The interaction will be technical communication but not technical direction. Per the technical direction clause EPAAR 1552.237-71 of the contract, the PO and the WAM or alternate WAM are the sole representatives of the CO authorized to provide technical direction.

WORK ASSIGNMENT MANAGER: Susan Peterson

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-27

TITLE: Chemical Safety for Sustainability (CSS) meetings support

PERIOD OF PERFORMANCE: CO Approval – October 31, 2014

I. PURPOSE:

The purpose of this Work Assignment is to provide administrative and logistical/facilitation support services for up to three face-to-face meetings for the Chemical Safety for Sustainability (CSS) research program within the Office of Research and Development (ORD). The meetings will be held in the Research Triangle Park, NC. This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

II. BACKGROUND:

Chemicals are a lynchpin of innovation in the American economy, and moving toward sustainable innovation requires designing, producing, and using chemicals in safer ways. Information and methods are needed to make better-informed, more-timely decisions about chemicals, many of which have not been thoroughly evaluated for potential risks to human health and the environment. EPA's chemical safety research is designed to meet this challenge and supports the Agency priority of reducing risks associated with exposure to chemicals in commerce, the environment, products and food.

The CSS Strategic Research Action Plan 2012-2016 (StRAP) provides the overall framework for CSS research. Fiscal year 2015 (FY15) planning presented an opportunity to conduct a mid-StRAP review of the program and look for ways to integrate the research, enhance transdisciplinary collaboration, promote and foster innovation, enhance transparency and access to CSS products, and significantly amplify the impact of this important research. The addendum to the CSS 2012-2016 StRAP was developed to facilitate integration of the CSS research program. Concurrently, ORD is beginning to gather input from stakeholders and partners in identifying the strategic directions necessary to develop an update to the StRAP for 2016-2019. The CSS research program is looking for logistical support for meetings related to existing research projects as well as coordinating with our partners and researchers across ORD, for FY15 planning and drafting the CSS StRAP update.

III. STATEMENT OF WORK:

A. Objective:

The overall objective of this work assignment (WA) is to provide administrative and logistical support for a minimum of three (3) meetings in support of CSS research program. Support will include planning for meeting and logistics, onsite meeting support and facilitation, a may include a summary report (including meeting and breakout discussion notes), and communication activities related to the meetings. The programs annual partner meeting dates are May 5-6, 2014 for the CSS Connectome partner meeting in Research Triangle Park (RTP). The CSS StRAP update planning meeting (dates TBD) will also be in RTP. EPA anticipates

the Connectome meeting to have approximately 80 - 100 participants. The other meetings will be considerably smaller with less than 50 expected. This work assignment does not include logistical support related to securing a facility or any meeting rooms. EPA has or will reserve its own meeting room space for these meetings. Administrative and logistical support shall consist of the following tasks:

B. Specific Requirements (Tasks):

- 1. A kick-off meeting shall be held (in person and/or by phone) between the Contractor and WAM to clarify or address questions. The contractor shall maintain communication with the EPA WA Manager (WAM) through weekly phone calls or email updates.
- 2. <u>Pre-meeting support:</u> Administrative and logistical support services for each meeting may include:
 - Develop a registration mechanism and coordinating registration, including maintaining a list of participants.
 - Provide participants local information about hotels, restaurants, directions, transportation (airport, airport transportation, etc).
 - Preparing folders for distribution to attendees at registration including final agenda, meeting roster, name badges and other meeting materials.
 - Working with EPA's onsite facility staff to ensure meeting rooms have AV equipment including microphone, laptop computer, projectors, screen, flip charts, tape, markers etc.
 - Setting up webinar, conference call and if applicable video conference capability for remote participation.

3. Onsite Logistical Support and Reporting

- Providing staff to support the meeting onsite.
- Capturing notes during the discussion including the plenary sessions and breakout groups. The notes should highlight key decisions and action items.
- Managing the registration table to ensure participants sign in, receive the meeting materials and handle any problems workshop participants may encounter.
- Update attendee list at the end of the workshop (remove no-shows, add walk-ins).
- Providing on-site liaison services to work with facility staff to trouble-shoot any problem situations related to AV support or break-out room set-up.
- Summarize in a report all meeting discussions including key decisions and actions items in a postmeeting summary report. This report should include a listing of all meeting attendees.

IV. SCHEDULE OF DELIVERABLES

The following table provides a complete list of required work assignment tasks that are to be completed as part of this contract.

Work Assignment Task	Required Completion Date
Initial contact (listed above) shall be performed.	Within 3 days of award
Establish website for on-line registration	April 15th, 2014
Submit electronic copies of registration lists and registration materials;	Two working days before Connectome meeting
Submit updated list of registered attendees (including walk-ins), electronic version of presentation materials, and any materials submitted by presenters prior to or following the meeting.	Ten working days following Connectome meeting
Post-meeting final report(s)	Ten working days following each meeting

V. Notice Regarding Guidance Provided Under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

VI. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

Travel: Any non-local travel directly chargeable to this work assignment shall be submitted and approved by the Project Officer prior to the travel (see contract clause Local LC-31-08, Approval of Contractor Travel). It is expected that the Contractor will be requested to participate in a 2-day workshop in the Research Triangle (NC) area on dates to be determined.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green

Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at http://www.epa.gov/oppt/greenmeetings/.

VII. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM) Monica Linnenbrink 919-541-1522 <u>Linnenbrink.monica@epa.gov</u>

Alternate WAM Michael Loughran 202-564-6686 Loughran.Michael@epa.gov

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-28

TITLE: Workshop to Obtain Peer Input on Draft Materials for the Integrated Science Assessment for Sulfur Oxides (SO_X) – Health Criteria

Principal Section & Paragraph of SOW: A. Assessment Issues and Documents

PERIOD OF PERFORMANCE: CO Approval – October 31, 2014

I. PURPOSE

The purpose of this work assignment is to provide administrative and logistical support for an online workshop, planned during late May or early June 2014, to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA). This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

II. BACKGROUND

Sections 108 and 109 of the Clean Air Act require periodic review and, if appropriate, revisions of the national ambient air quality standards (NAAQS) and the air quality criteria on which they are based. EPA held a kickoff science and policy workshop to initiate a review of the primary (health-based) NAAQS for sulfur oxides (SO_X) in June 2013. Subsequent to the workshop, EPA is developing an integrated review plan that will outline the schedule, process, and key policy-relevant issues that will generally be used to frame the science assessment, risk/exposure assessment, and policy assessment documents. These documents will provide the foundation to inform Agency decision-makers throughout the review of the primary SO_X NAAQS.

As part of the initial development of the Integrated Science Assessment (ISA), EPA and external authors prepare draft sections on discipline-specific topics related to ambient concentrations, exposure, and health effects of SO_X. Prior to integration of the sections and evaluation of the weight of evidence, EPA solicits input from subject matter experts on the scope and content of these draft sections. EPA plans to hold a one-day workshop via webinar for this purpose during late May or early June 2014, during which workshop participants shall be asked to comment on sections related to their area of expertise. The workshop will be online only, and will be hosted at EPA's main Research Triangle Park facility. The workshop discussions will be considered as the Agency finalizes the 1st External Review Draft ISA.

III. STATEMENT OF WORK

A. Objective

The overall objective of this work assignment (WA) is to provide administrative and logistical support for the webinar workshop described above. The goal of the workshop is to solicit input and comment from subject matter experts on draft sections of the ISA for SO_X – Health Criteria. Workshop panelists will be expected to read the draft materials, provide written comments, and participate in discussions at the workshop regarding the scope and content of the sections. The workshop discussions will provide important input as EPA considers

how to integrate evidence across disciplines and evaluate the weight of evidence regarding health effects of SO_X. Each session panel shall consist of several experts (EPA or non-EPA) from a range of disciplines including epidemiology, toxicology, air quality/exposure, fate and transport, toxicokinetics, and risk/exposure assessment. The webinar shall have an expected attendance of approximately 100 participants. Panelists shall provide draft written comments prior to the workshop and final written comments following the workshop. Administrative and logistical support shall consist of the following tasks:

B. Specific Requirements (Tasks)

- 1. A kick-off meeting shall be held (in person and/or by phone) note to exceed 1 hour between the Contractor and the EPA Work Assignment Manager (WAM) to clarify or address questions. The contractor shall maintain communication with the WAM through weekly phone calls or email updates.
- 2. Identify and contact non-federal experts with broad knowledge and expertise in the areas of air pollution epidemiology, toxicology, exposure/atmospheric sciences, fate and transport, and risk/exposure assessment with the goal of recruiting approximately 12-15 of these experts to participate in the workshop. The date and time of the webinar shall be in late May or early June 2014, based on availability of the participants, and subject to approval by the WAM. Arrange logistical support (e.g., webinar access) and appropriate compensation for the time and effort of the non-federal experts. Potential invitees shall be asked to submit a bio-sketch for assessing their qualifications and must be approved by the WAM.
- 3. Compile draft SO_X ISA sections provided by EPA and format them for distribution to the panelists. Formatting shall include bibliographic citations, section numbers, line numbers, and other basic features to facilitate readability. The Contractor shall provide formatted sections to EPA for review and technical direction approximately one week prior to the deliverable due date. Upon approval by EPA, the Contractor shall send the materials to the panelists.
- 4. Set up a website for online registration and meeting material availability for panelists as well as other EPA and non-EPA attendees.
- 5. Compile draft written comments from each of the panelists. Circulate comments to EPA and other panelists approximately one week prior to the workshop.
- 6. Prepare and make available electronic and paper copies of meeting materials, including registration lists and other registration materials (preliminary and final agendas will be provided by EPA.) Coordinate facilities for presentation of the material (e.g., PowerPoint presentations). The Contractor shall provide draft materials to the WAM for review and technical direction approximately one week prior to the deliverable due date.
- 7. Provide assistance (including onsite assistance) to EPA at the time of the workshop. This includes providing on-site staff throughout the length of the workshop to host the webinar and coordinate with facility staff during planning, set-up, implementation and closeout of the event and to assist workshop participants, as appropriate.
- 8. Compile and maintain mailing list and final attendance list of all attendees, both EPA and non-EPA. Update attendee list at the end of the workshop. Compile final written comments from each of the panelists.

SCHEDULE OF DELIVERABLES V.

<u>Deliverables</u>	Due Dates
Initial Contact (listed above) shall be performed.	Within 3 days of award
2. Invite and confirm experts for participation in panel discussions.	April 25, 2014
3. Send formatted draft materials to panelists	May 2, 2014
4. Establish website for on-line registration and meeting materials.	May 2, 2014
5. Compile draft written comments from the panelists.	Approximately one week prior to the webinar
6. Make meeting materials available to panelists and attendees.	Approximately one week prior to the webinar
7. Provide onsite and other logistical assistance for the webinar.	Date of the webinar
8. Submit final list of registered attendees, electronic version of presentation materials, any materials submitted by presenters at or following the meeting, and panelists' final written comments.	Approximately one week following the webinar

VI. Notice Regarding Guidance Provided Under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

VII. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

Travel: Any non-local travel directly chargeable to this work assignment shall be submitted and approved by the Project Officer prior to the travel (see contract clause Local LC-31-08, Approval of Contractor Travel). It is expected that the Contractor will be requested to participate in a 2-day workshop in the Research Triangle (NC) area on dates to be determined.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at http://www.epa.gov/oppt/greenmeetings/.

VIII. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM) Ellen Kirrane, PhD 919-541-1340 kirrane.ellen@epa.gov

Alternate WAM
Steven Dutton, PhD
919-541-5035
dutton.steven@epa.gov

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-29

<u>TITLE</u>: Expert Consultation on Considerations Regarding Exposure Measures in Epidemiological Studies of Phthalates for IRIS Assessments

Specify Section & Paragraph SOW:

- A. Assessment Issues and Documents
- 1. Human Health Assessment Documents
- D. Analysis, Document and Issue Paper Preparation
- E. Risk Assessment Support

PERIOD OF PERFORMANCE: CO approval through 11/30/2014

I. PURPOSE

The purpose of this work assignment (WA) is to identify, recruit, and manage one or more qualified scientists to provide consultative services with the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (hereinafter NCEA). The topics on which EPA seeks advice relate to several issues related to phthalate exposure assessment methods in epidemiological studies. These issues include but are not limited to 1) interpretation of metabolites (and methods for summing common metabolites of a given phthalate), 2) comparability between measures in different tissues (e.g., urine, serum, breast milk, seminal fluid, amniotic fluid), 3) reliability of spot urine (compared with 24-hour urine) samples; reliability of a single sample for characterizing exposure over different time periods (e.g., days, weeks, months, years); comparison of reliability data by demographic group (e.g., during pregnancy, in children), 4) appropriateness of different methods used to adjust for urine volume (e.g., creatinine adjustment, specific gravity adjustment), taking into consideration demographic group and type of outcome, and 6) trends in specific phthalate exposures over the past 10-15 years in the United States and in other countries. For each of these issues, EPA initially seeks advice regarding each of 7 specific phthalates: diethyl phthalate (DEP), di-isononyl phthalate (DiNP), dibutyl phthalate (DBP), di-isobutyl phthalate (DiBP), butyl benzyl phthalate (BBzP), diethylhexyl phthalate (DEHP), and diisodecyl phthalate (DiDP); additional phthalates may subsequently be added to this list.

II. BACKGROUND

EPA is currently developing or considering developing Toxicological Reviews of 7 phthalates: DEP, DiNP, DBP, DiBP, BBzP, DEHP, and DiDP. The Agency now seeks to recruit one or more experts in exposure assessment in epidemiological studies of phthalates to provide guidance and clarification regarding the state of the science with respect to this area. The expert(s) shall be asked to prepare a draft summary of relevant research pertaining to specific exposure measurement issues that may inform the interpretation of epidemiological studies included in the draft Toxicological Reviews.

The overall objective of this WA is to identify, recruit, and manage one or more experts to provide guidance and clarification regarding interpretation of exposure measures in epidemiological studies of phthalates, and to provide a transparent and comprehensive review of published studies pertaining to specific issues related to phthalate exposure assessment methods in epidemiological studies. The recruited scientist(s) will conduct a review of relevant primary source data pertaining to the specified research questions, prepare a tabular display

of data from these sources, and prepare a draft synthesis of conclusions that can be drawn from the data. It is expected that this material could be the basis for one or more publications to be developed in collaboration with EPA staff members.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan and QAPP

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan and which shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the areas of project management and communication skills.

The contractor must prepare a QAPP. In the QAPP the Contractor must address how it will consider the use of existing data to carry out this PWS. Existing data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents - "<u>EPA Quality Manual for Environmental Programs EPA CIO 2105-P-01-0</u>"

(<u>http://www.epa.gov/irmpoli8/policies/2105P010.pdf</u>, "<u>EPA Requirements for Quality Assurance Project Plans (QA/R-5)</u>", and "<u>Guidance for Quality Assurance Project Plans (G-5)</u>", http://www.epa.gov/quality/qs-docs/g5-final.pdf.

The QAPP shall be submitted simultaneously with the Work Plan for approval.

Task 3: Identify and Recruit Expert(s)

The Contractor shall identify and contact one or more federal or non-federal experts with an expertise in exposure assessment in epidemiological studies of phthalates. Potential invitees shall be asked to submit a bio-sketch for assessing their qualifications and must be approved by the WAM.

Task 4: Provide Background Material to Recruited Expert(s)

The Contractor shall provide EPA materials to the selected expert(s). This material will include a copy of the QAPP, a list of specific research questions, list of specific phthalates, and example of a synthesis of conclusions.

Task 5: Arrange Periodic Teleconferences with Expert(s)

The Contractor shall arrange and provide logistical support for teleconferences with WAM, appropriate EPA and contractor staff, and selected expert(s) at the initiation of the project and after delivery to EPA of each of the deliverables.

Task 6: Manage Written Materials Prepared by Expert(s)

The Contractor shall manage the collection of the written material prepared by the expert(s). The Contractor shall provide the WAM with these materials within 2 days of their receipt by the Contractor. EPA anticipates that material to be provided by the expert(s) will include (but is not limited to) 1) list of relevant references and description of search strategy used to identify and select these references, 2) tabular display of data relating to specific questions, 3) draft synthesis, and 4) full report. The tabular display and draft synthesis may be prepared in two sets, with a selection of 3-4 phthalates (to be determined by EPA) in each set (e.g., set 1 including DiNP, DiBp, BBP, and DiDP; set 2 including DBP, DEHP, and DEP).

Task 7: Coordinate literature tagging in HERO

The Contractor shall coordinate uploading of relevant references and tagging in HERO.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. All deliverables shall be provided in electronic format in Microsoft Word.

V. DELIVERABLES AND SCHEDULE

Task	Deliverable Due Date
Task 1. Initial Conference Call	3 days after receipt of Work Assignment
Task 2. Work Plan and Staffing Plan	15 days after receipt of Work Assignment
Task 3: Identify and Recruit Expert(s)	No more than 30 days after award
Task 4: Provide Background Material to Recruited Expert(s)	No more than 5 days after recruitment of expert(s)
Task 5: Arrange Periodic Teleconferences with Expert(s)	No more than one week after recruitment of expert or submission of material to EPA
 Task 6: Manage Written Materials Prepared by Expert(s): a) Initial list of relevant references and description of search strategy used to identify and select these references b) tabular display of data relating to specific questions for first set of phthalates c) draft synthesis for first set of phthalates d) tabular display of data relating to specific questions for second set of phthalates e) draft synthesis for second set of phthalates f) full report and final list of references 	Within 3 days of receipt from expert(s)
Task 7: Coordinate literature tagging in HERO	Within 2 weeks of receipt of full report

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
- 2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM, or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Glinda Cooper, Ph.D. Phone: 703-347-8636 Fax: 703-347-8689

Email: cooper.glinda@epa.gov

Alternate WAM:

Susan Rieth

Phone: 703-347-8582 Fax: 703-347-8689 e-mail: rieth.susan@epa.gov

Mailing Address:

U.S. Environmental Protection Agency Office of Research and Development National Center for Environmental Assessment (8601P) 1200 Pennsylvania Ave. NW Washington, DC 20460

Overnight Delivery location: Two Potomac Yard (N-8315) 2733 S. Crystal Drive Arlington, VA 22202

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 0-30

TITLE: Informational Teleconference for Evaluating Epidemiological Studies of Allergy and Asthma

Specify Section & Paragraph SOW:

- A. Assessment Issues and Documents
- 1. Human Health Assessment Documents
- D. Analysis, Document and Issue Paper Preparation
- E. Risk Assessment Support

PERIOD OF PERFORMANCE: Award to October 31, 2014

I. PURPOSE

The purpose of this work assignment (WA) is to identify, recruit, and manage qualified scientists to participate in a teleconference, planned for June/July 2014, with the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA). The teleconference aims to discuss definitions relating to allergy and asthma relevant to the hazard identification sections of the draft Toxicological Review of Formaldehyde. The topics which EPA seeks advice include but are not limited to 1(a) instruments (e.g., questionnaires) and definitions of asthma used in epidemiological studies conducted in residential, school, and occupational settings and 1(b) appropriate characterization of what health outcomes these asthma-related studies are examining; and 2(a) questionnaire-based instruments and other approaches to assess allergy history or allergic response in epidemiological studies conducted in residential, school, and occupational settings and 2(b) appropriate characterization of what these allergy-related studies are examining.

II. BACKGROUND

EPA is currently revising the draft formaldehyde assessment based on suggestions received from National Academy of Sciences (2011). The Agency plans to hold a teleconference in June/July 2014 to receive input from external experts in epidemiological studies of asthma and allergy. Prior to this teleconference, EPA scientists will compile information on the methods used to define the outcome (health effect) in epidemiological studies examining prevalence or incidence of asthma or allergy. The details of the outcome assessment and the prevalence of the specified outcome from approximately 20-30 example studies will be abstracted into a tabular format. The Agency now seeks to recruit experts in asthma and allergy epidemiology to provide guidance and clarification regarding the state of the science with respect to defining and assessing these outcomes. Teleconference participants shall be asked to discuss key concepts in this type of epidemiological research that may inform the science-relevant issues to be captured in the draft Toxicological Review of Formaldehyde.

The overall objective of this WA is to identify, recruit, and manage expert scientists to participate in a teleconference on topics relevant to the allergy and asthma hazard identification. Recruited scientists will participate in an open dialogue on science-relevant issues related to methods used to assess history of asthma or allergy in epidemiological studies and provide a short written synopsis of their individual conclusions following the teleconference. It is expected that one teleconference will be conducted focusing on asthma and one teleconference will be conducted focusing on allergy; each teleconference will have approximately 6-12 participants, including 4-6 invited external experts and 3-6 EPA staff members. One or more expert can serve on both of the panels.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan and Staffing Plan

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan and which shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the areas of project management and communication skills.

Task 3: Identify and Recruit Experts for Participation in Teleconference Panels

The Contractor shall identify federal and non-federal experts with an expertise in epidemiological studies of asthma or allergy within the context of research on environmental or occupational exposures. The overall expertise of the panels (one for asthma, one for allergy) should be able to provide a scientific discussion/debate on the reliability (sensitivity, specificity) of different approaches to assessing asthma and allergy in a variety of populations (children, adult general population, and workers). Potential invitees shall be asked to submit a biosketch for ensuring they meet minimum technical qualifications and must be approved by the WAM.

Task 4: Make Arrangements for Teleconferences

The Contractor shall identify an equally convenient time for the participants and EPA staff to hold two teleconferences in June or July 2014 (each lasting approximately 2 hours).

The Contractor shall provide EPA materials to experts prior to the teleconference. The experts are not expected to review the full study reports; rather, their review should be limited to the details of the methods that are abstracted and provided by EPA. The total length of this material is estimated to be 4-6 pages of a tabular display of information. Specific charge questions to guide the teleconference discussions will also be provided by EPA.

The Contractor shall provide logistical support for the teleconferences; the conference line will be provided by EPA.

Task 5: Manage Written Summaries

The Contractor shall manage the creation and collection of brief written summaries (< 5 pages) from the invitees. After each teleconference discussion, invitees shall be asked to provide a brief written evaluation of the specific charge questions provided to them prior to the teleconference. The Contractor shall provide the WAM with these summaries within 2 weeks after the teleconference.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. All deliverables shall be provided in electronic format in Microsoft Word.

V. DELIVERABLES AND SCHEDULE

Task	Deliverable Due Date				
Task 1. Initial Conference Call	3 days after receipt of Work Assignment				
Task 2. Staffing Plan	15 days after receipt of Work Assignment				
Task 3: Identify and Recruit Experts	No more than 30 days after award				
Task 4: Make Arrangements for Teleconferences	No more than 15 days after recruitment of experts for each teleconference panel				
Task 5: Manage Written Summaries	No more than two weeks after each teleconference				

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

- All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
- The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- Formulation of Agency policy
- Selection of Agency priorities
- Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM, or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Glinda Cooper, Ph.D.

Phone: 703-347-8636 Fax: 703-347-8689

Email: cooper.glinda@epa.gov

Alternate WAM

Susan Rieth

Phone: 703-347-8582 Fax: 703-347-8689

e-mail: rieth.susan@epa.gov

Overnight Delivery location: U.S. Environmental Protection Agency

Office of Research and Development, National Center for Environmental Assessment

Two Potomac Yard (N-7811), 2733 S. Crystal Drive

Arlington, VA 22202

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